Attachment 7

Consumer Articles in the News

THE WALL STREET JOURNAL. ONLINE

March 15, 2007

WSJ ONLINE/HARRIS INTERACTIVE HEALTH-CARE POLL

Many Americans Disregard Doctors' Course of Treatment

THE WALL STREET JOURNAL ONLINE
March 15, 2007

A quarter of Americans say they have left a drug prescription unfilled because they felt it was unneeded and a fifth have obtained a second opinion because they felt their doctors' recommendations were too aggressive.

In all, 44% of Americans say they or an immediate family member have ignored a doctor's course of treatment or sought a second opinion because they felt the doctor's orders were unnecessary or overly aggressive, according to a Wall Street Journal Online/Harris Interactive health-care poll.

In addition to the 27% who have left a prescription unfilled and 20% who have sought a second opinion, 13% have avoided getting a diagnostic test, 7% have opted against a surgical procedure and 7% have changed doctors because they felt their doctor's recommended treatment was too aggressive. Respondents were presented with several scenarios and were able to select more than one that applied to them or a family member.

Among survey respondents who said they have chosen not to follow a doctor's recommendations, 89% said nothing negative happened as a result. Eleven percent reported some sort of negative effect, such as worsening health conditions and lost time from work.

The survey found 43% of Americans say they are concerned about receiving too many treatments or overly aggressive treatment when they are sick or in need of medical care. In a survey conducted two years ago, 50% said they felt that way.

About 52% of Americans believe doctors overtreat patients because of concerns about malpractice lawsuits, while 41% say doctors do so "to make more money" and 44% say "to meet patients' demands."

Still, Americans seem to believe that undertreatment is a problem, too. When asked how often they believe patients are undertreated, 29% said often and 55% said sometimes.

See full results of the poll:

"Based on what you know or have heard, how often do you think patients who have medical conditions experience problems because of...?"

Base: All adults

		Often/Sometimes (Net)	Often	Sometimes	Rarely/Never (Net)	Rarely	Never
Being **over-treated**, for example, by getting too many treatments or by getting more aggressive treatment than is appropriate	2005	72%	22%	50%	28%	22%	6%
	2007	73	19	54	27	22	5
Being **under-treated**, for example by getting too few treatments or by getting less aggressive treatment than is appropriate	2005	83	31	51	17	13	5
	2007	83	29	55	17	14	3

Note: Percentages may not add up to exactly 100 percent due to rounding.

* * *

"How concerned are you, personally, about receiving too many treatments or overly aggressive treatment when you are sick or in need of medical care?"

Base: All adults

	2005	2007
Very/Somewhat Concerned (Net)	50%	43%
Very concerned	14	10
Somewhat concerned	37	33
Not Very/At All Concerned (Net)	50	57
Not very concerned	36	44
Not at all concerned	14	13

Note: Percentages may not add up to 100 percent due to rounding.

* * *

"Which of the following, if any, have you ever done when your doctor recommended a particular course of treatment for you or an immediate family member? Please select all that apply."

Base: All adults

	2005	2007
Did not fill a prescription that your doctor gave you because you felt it was unnecessary	32%	27%
Got a second opinion from another doctor because you thought your doctor's recommendations were too aggressive	21	20
Did not get a diagnostic test that your doctor recommended because you felt it was unnecessary	16	13
Did not get a surgical procedure that your doctor recommended because you felt it was unnecessary	10	7
Changed doctors because you felt that your doctor's approach was too aggressive	9	7
None of these	48	56

Note: Multiple-response question.

* * *

"What, if anything, happened to your or your family member as a result of choosing not to follow your doctor's recommendations? If you had more than one such experience, please answer for the most recent one. Please select all that apply."

Base: Respondents who chose to forgo recommended treatment

	TOTAL
Experienced a new medical problem or complication	2%
Required hospitalization	2
Lost time from work or school	4
Health got worse	3
Had to go to the emergency room	3
Some other type of problem	3

Nothing negative happened as a result	89

Note: Multiple-response question.

* * *

"Based on what you know or have heard, what do you think are the reasons that doctors sometimes over-treat patients, for example by providing too many treatments or overly aggressive treatments?"

Base: All adults

	2005	2007
Because of concerns about malpractice lawsuits	53%	52%
To make more money	45	41
To meet patients' demands	45	44
To make fast and easy decisions	31	25
Because of misleading information they receive from prescription drug and medical device companies	30	27
Because of a faulty medical diagnosis	27	25
To give patients more reason to hope	16	13
Other	6	7
Don't know	9	16

Note: Multiple-response question.

Methodology:
Harris Interactive conducted this online survey in the U.S., March 5-7, 2007, among a nationwide cross section of 2,673 adults. Figures for age, gender, race/ethnicity, education, income and region were weighted where necessary to align with population proportions. Propensity score weighting was also used to adjust for respondents' propensity to be online. In theory, with probability samples of this size, one can say with 95% certainty that the overall results have a sampling error of +/- 3 percentage points of what they would be if the entire U.S. adult population had been polled with complete accuracy. This online sample is not a probability sample.

About Harris Interactive

Harris Interactive is a world-wide market research and consulting firm, best known for The Harris Poll and its use of the Internet to conduct scientifically accurate market research. For more information, see www.harrisinteractive.com[1]. To become a participant in The Harris Poll Online and join future online surveys, see www.harrispollonline.com[2].

URL for this article:
http://online.wsj.com/article/SB117371341275134217.html

Hyperlinks in this Article:
(1) http://www.harrisinteractive.com
(2) http://www.harrispollonline.com

Public Ed

Karen Abbe/Pharmacy/DCANotes
03/13/2007 08:17 AM

To Virginia Herold/Pharmacy/DCANotes@DCANotes
cc
bcc
Subject San Diego Union-Tribune: Health illiteracy hampers wellness

The San Diego Union-Tribune.

JANE E. BRODY

Health illiteracy hampers wellness

March 13, 2007

How often have you left a doctor's office wondering just what you were told about your health, or what exactly you were supposed to be doing to relieve or prevent a problem? If you are a typical patient, you remember less than half of what your doctor tries to explain.

National studies have found that "health literacy" is remarkably low, with more than 90 million Americans unable to adequately understand basic health information. The studies show that this obstacle "affects people of all ages, races, income and education levels," Dr. Richard H. Carmona, the U.S. surgeon general, wrote in the August issue of The Journal of General Internal Medicine.

The fallout is anything but trivial. Researchers have found that poor health literacy, which is especially prevalent among the elderly, results in poor adherence to prescription instructions, infrequent use of preventive medical services, increased hospitalizations and visits to the emergency room and worse control of chronic diseases.

The consequences are poorer health and greater medical costs. All because doctors fail to speak to patients in plain English (or Spanish or Chinese or any other language) and fail to make sure that patients understand what they are told and what they are supposed to do and why.

In a study published in the internal medicine journal, conducted among 2,512 elderly men and women living on their own in Memphis and Pittsburgh, those with limited health literacy were nearly twice as likely to die in a five-year period as were those with adequate health literacy. That held true even when age, race, socioeconomic factors, current health conditions, health care access and health-related behaviors were taken into account.

Among the many problems resulting from limited health literacy are misinterpretations of warning labels on prescription drugs. For example, among 251 adults attending a primary care clinic in Shreveport, La., those with low literacy were three times more likely to misunderstand warnings than the more literate.

A main obstacle has been the decreased time patients can spend with their doctors, dictated largely by managed care and other medical reimbursement plans.

A second hurdle is the embarrassment that patients with limited health literacy experience when they do not understand what the doctor has said. And, of course, asking for clarification is seriously impeded by the imbalance in power between the white-coated physician and the paper-wrapped patient. Even when conversations are conducted in the doctor's office with a fully clothed patient, patients are reluctant to ask questions.

More medical schools, residency programs and continuing education programs for practicing physicians need to include training in clinical communication skills.

Dr. Sunil Kripalani of the Emory University School of Medicine in Atlanta and Dr. Barry D. Weiss of the University of Arizona College of Medicine in Tucson suggest these strategies:

Doctors should assess the patient's baseline understanding before providing extensive information:

"Before we go on, could you tell me what you already know about high blood pressure?"

Doctors should use plain language, not medical jargon, vague terms and words that may have different meanings to a lay person. They should say chest pain instead of angina, hamburger instead of red meat.

To encourage patients to ask questions, doctors should ask, "What questions do you have?" rather than, "Do you have any questions?"

Doctors should confirm the patient's understanding by saying, "I always ask my patients to repeat things back to make sure I have explained them clearly." Or, if a new skill like using an inhaler was taught, the doctor should have the patient demonstrate the action.

Then, as fail-safe measures, the doctor should provide written instructions and educational material for the patient and family to review at home.

Do not wait until doctors become better at communicating. If you want the best medical care, you have to take the initiative. If the doctor says something you do not understand, ask that it be repeated in simpler language. If you are given a new set of instructions, repeat them back to the doctor to confirm your understanding. If you are given a new device to use, demonstrate how you think you are to use it.

Insist that conversations about serious medical matters take place when you are dressed and in the doctor's office. Take notes or take along an advocate who can take notes for you. Better yet, tape-record the conversation to replay it at home for you and your family or another doctor.

Public Ed

Karen Abbe/Pharmacy/DCANotes
03/06/2007 08:41 AM

To Virginia Herold/Pharmacy/DCANotes@DCANotes
cc
bcc
Subject ASHP: Accidental Poisonings Can Happen During Day-to-Day Routines

American Society of Health-System Pharmacists

Press Releases and Announcements

Accidental Poisonings Can Happen During Day-to-Day Routines

3/1/2007

With more than 90 percent of poisonings occurring in the home and more than 19 million Americans caring for someone over the age of 75, caregivers and family members of children and seniors play a critical role in prevention of poisonings. The American Society of Health-System Pharmacists (ASHP) recognizes the importance of providing caregivers with poison prevention information during National Poison Prevention Week, March 18-24.

An estimated 44 percent of Americans have an aging parent and a young child for whom they care for. The majority of non-fatal poisonings occur in children younger than six years old and seniors who take multiple medications are at increased risk of accidental poisonings.

"The fact is most accidental poisonings happen among our youngest and oldest populations who are dependant on a caregiver," said Daniel J. Cobaugh, Pharm.D., FAACT, DABAT, director of research for the ASHP Research and Education Foundation. "Accidental poisonings can take many shapes such as when a child thinks medicine is candy or when a senior becomes confused and takes an additional dose of their medicine."

To help prevent poisonings from happening, ASHP has developed practical tips for caregivers of children and seniors.

For caregivers of seniors, ASHP recommends following these six tips:

Keep a list of your medicines. A written record of medications including medication name, dosage, and frequency, is an important tool to have during physician visits and in case of an emergency. It is also important to record any over-the-counter (OTC) medications, vitamins, supplements, or herbal products are being taken. Having a family member or caregiver keep a copy of this list is also invaluable.

Communicate. Stay informed of all medications, including non-prescription medicines and dietary supplements; this will help reduce the chances of an interaction.

Learn about their medicines. Ask the doctor or pharmacist to explain each medication, the food and medicines to be avoided, and possible reactions and side effects. Family members or caregivers should also be given this information.

Use one pharmacy. Many seniors receive prescriptions from more than one doctor, making drug interactions more likely. By using one pharmacy, all of the prescriptions are consolidated and the pharmacist can check for possible interactions between medicines. It is still important, however, to keep in mind that over-the-counter medicines should also be considered, as overdoses could occur this way.

Keep a journal. Make note of all symptoms, especially after taking medicines. Painful or unexpected side effects

such as dizziness, nausea, or drowsiness, may signal a need for adjusting the medication regimen.

Maintain a schedule. Holding to a routine can decrease the chances of missing dosages or taking more than needed. The use of a pillbox may help with this.

For caregivers of children, ASHP recommends following these five tips:

Use original child-resistant containers. Use child-resistant closures on medicines and other products and always keep all medications (both prescription, nonprescription, and dietary supplements) in their original child-resistant containers.

Always call medicine "medicine". Avoid calling medicine "candy" in order to get the child to take the medicine.

Check your medicines periodically for expiration dates. If a medication is not dated, consider it expired six months after purchase.

Avoid putting medicines in open trash containers. This is especially important in the kitchen or bathroom because many adult medications can be deadly to small children.

Keep medications secure. Keep all medicines, including OTC's, herbals, vitmins, and supplements, out of reach of children, or in a locked cabinet.

"The good news is that healthcare professionals and caregivers can work together to create a solution," said Cobaugh. "By being active participants in their healthcare, family members and caregivers can be informed on the best ways to prevent an accidental poisoning."

Caregivers and family members should post the poison control center number (800.222.1222) visibly in the home, Cobaugh said. "Many poison control centers are staffed by pharmacists, whose training makes them uniquely qualified to advise caregivers in the event of an emergency."

Medication tips and information on using medicine safely can be found on ASHP's consumer Web site, www.SafeMedication.com.

For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 30,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students. For more information about the wide array of ASHP activities and the many ways in which pharmacists help people make the best use of medicines, visit ASHP's Web site, www.ashp.org , or its consumer Web site, www.SafeMedication.com .

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Med Errors

Karen Abbe/Pharmacy/DCANotes
03/07/2007 11:20 AM

To Virginia Herold/Pharmacy/DCANotes@DCANotes
cc
bcc
Subject Washington Post: Risk of Errors In Medication Said to Rise With Surgery

washingtonpost.com

Risk of Errors In Medication Said to Rise With Surgery

By Rob Stein
Washington Post Staff Writer
Tuesday, March 6, 2007; A08

Patients going under the knife face a significant risk of becoming the victim of a medical error involving medication, according to a report being released today.

The report, the largest examination of medication errors before, during and after surgery, found that operations are among the riskiest times for mistakes involving drugs.

The report was prepared by U.S. Pharmacopeia, a private group that sets standards for the drug industry. It has been gathering reports from hospitals nationwide about medication mistakes.

Its latest report is based on data voluntarily supplied by more than 400 hospitals about medication errors from 1998 to 2005 that occurred during outpatient surgery, in preparation for surgery, in the operating room and in recovery.

A total of 11,239 errors were reported, including giving the wrong drug or the wrong dose, or giving it at the wrong time.

Five percent of the mistakes caused harm, making surgery one of the most dangerous times for medication mistakes.

Mistakes during the operation itself were the most likely to result in harm.

In most cases the harm was temporary, but four deaths resulted from the errors. The mistakes were most dangerous to children, and the most common involved antibiotics and painkillers.

In addition to encouraging hospitals to take steps to reduce errors, the findings intend to alert patients and their families to be vigilant to protect themselves.

"We hope this will impact practice and make the whole system safe by bringing awareness to the topic," said Rodney Hicks, who helped prepare the report.

THE HENRY J. KAISER FAMILY FOUNDATION kaisernetwork.org

Kaiser Daily Health Policy Report

Tuesday, March 13, 2007

Prescription Drugs

Generic Medications Often More Expensive Than Expected

The *Wall Street Journal* on Tuesday examined how the prices of generic medications "can vary wildly and may not be nearly as cheap as expected." Patients with prescription drug coverage in most cases pay the lowest copayments for generic medications when they reach the market, but those without coverage are subject to different, and in some cases high, prices charged by pharmacies. According to the *Journal*, at a "time when policymakers are searching for ways to cut health care costs, generic drugs are often viewed as one of the most straightforward solutions," but generic versions of a "number of other notable drugs that came off patent recently" have "failed to deliver big savings in many cases." Jim Yocum -- executive vice president of DestinationRx, a pharmacy data and software company -- said, "We're not seeing that sharp a drop-off" in prices among generic medications that have reached the market in recent years, adding, "We're just not seeing it."

Zocor

For example, although the price that health insurers pay for simvastatin -- the generic version of the anticholesterol medication Zocor, which lost patent protection in June 2006 -- has "dropped dramatically," the "price that pharmacies charge patients who pay cash remains high in many locations, with wide variations by vendor." Walgreens.com had charged $129.99 for 30 tablets of the 20-milligram dose of simvastatin, compared with $149.99 for Zocor. In late February, after a call from a reporter, walgreens.com reduced the price of simvastatin to $89.99. A walgreens.com spokesperson said that the company previously had the price of simvastatin under review. CVS.com had charged $108.99 for the same dose of simvastatin, compared with $154.99 for Zocor. Last week, after a call from a reporter, CVS.com announced plans to reduce the price of simvastatin to $79.99 as part of an "ongoing price analysis." Drugstore.com had charged $125 for the same dose of simvastatin, compared with $135.99 for Zocor. On Friday, after a call from a reporter, drugstore.com reduced the price of simvastatin to $27.99, a move that the company attributed to part of a regular review. A Rite Aid spokesperson last week said that the company charges $131.99 for the same dose of simvastatin, compared with $178.99 for Zocor. On Monday, the spokesperson said that the prices were inaccurate but did not provide revised prices (Rubenstein, *Wall Street Journal*, 3/13).

help make sure each set was complete before it was shipped to a surgeon, and to determine which parts or instruments were used or missing when the kits returned to Biomet.

Moreover, the U.S. Food and Drug Administration (FDA) is investigating how the use of a unique device identification (UDI) system, such as one making use of RFID technology, might improve patient safety by tracking medical devices in the supply chain (see FDA Reviews Comments on Device-ID System).

Public

Karen Abbe/Pharmacy/DCANotes
03/19/2007 10:58 AM

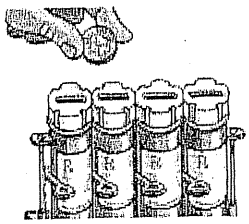
To Virginia Herold/Pharmacy/DCANotes@DCANotes
cc
bcc
Subject LA Times: Soothing the pain of prescription drugs' cost

Los Angeles Times latimes.com

Soothing the pain of prescription drugs' cost

Many people are unaware of money-saving options, and doctors often don't think to discuss it. So ask.

By Genevieve Bookwalter, Special to The Times
March 19, 2007



Theresamary JOHNSON is supposed to take nine prescriptions each day – 10 on Thursdays – for lung disease, high blood pressure, osteoporosis, heart disease, rheumatoid arthritis and lupus.

Sometimes she does. Sometimes, she can't afford to.

"I busted my buns to see I wasn't in poverty in my old age, and I feel like I'm getting dragged right into it," the 70-year-old Rio Linda, Calif., resident says.

Like Johnson, many Americans have trouble paying for prescription drugs. But as legislators, employers, insurance and drug companies wrestle with the issue, patient advocates say consumers could be doing more to lower their own drug costs.

In 2001, 12.7% of working-age adults with private insurance and chronic health conditions reported that they had skipped refills because of the cost; by 2003, that number had risen to 15.2%, according to the Center for Studying Health System Change.

Last year, more than 10% of the 39 million people enrolled in Medicare's prescription drug plan paid out-of-pocket for drugs that potentially cost hundreds of dollars, according to the Kaiser Family Foundation.

For people without health insurance, the burden of prescription drugs is entirely their own. The Census Bureau reported last year that 46.6 million people, or 15.9% of those living in the United States, are without health insurance. An additional 16 million are underinsured and often spend more than 10% of their incomes on medical care, according to a 2005 survey by the Commonwealth Fund, a private foundation dedicated to improving healthcare practice and policy.

Republican and Democratic lawmakers in Congress are backing legislation to legalize drug imports from Canada and other industrialized countries, where they're often cheaper, but such efforts are opposed by the Food and Drug Administration and the pharmaceutical lobby.

Meanwhile, the House has approved a bill that would allow the federal government to bargain over prescription drug prices for seniors and others covered by Medicare's drug plan. Although under

consideration in the Senate, President Bush has vowed to veto it, supporting a reliance on private enterprise instead.

As prescription drug sales rise – up 8.3% last year to $274.9 billion, according to a survey released this month by IMS Health – consumer advocates say patients need to start speaking up. With research, compromise and aggressive questions, many patients can reduce the amount of money they spend on prescription drugs.

When medicine bills get too high, "it is up to the patient to make the physician and pharmacist aware," said Dr. Derjung Mimi Tarn, an assistant professor of family medicine at UCLA's David Geffen School of Medicine.

Tarn illustrated that point in November with a study published in the American Journal of Managed Care. Her survey found that only a third of doctors discussed cost, insurance, supply, refills or money-saving generic drugs with patients when writing prescriptions. Only 2% of patients asked those questions, the study showed.

"Physicians aren't always aware of patient costs," Tarn said, "and patients are often intimidated or embarrassed to talk about cost issues with their physician."

Nor are patients taking advantage of other easily available, cost-saving measures.

Health plans, for example, regularly offer mail-order prescription drugs, with a three-month supply often rivaling the cost of a one-month supply at a brick-and-mortar pharmacy. Consumers who used these mail-order plans are expected to save as much as $85 billion through 2016, according to a study by the Lewin Group prepared for the Pharmaceutical Care Management Assn., which represents these discount pharmacies. But if all qualifying maintenance drugs were ordered through these pharmacies, the savings could double, the study showed.

And millions of patients qualify for programs that could provide them with free drugs – but are unaware of such assistance. Through the Partnership for Prescription Assistance, pharmaceutical companies and healthcare providers give free or low-cost drugs to the uninsured who make less than $41,300 for a family of four.

Since 2005, more than 3.5 million people have signed up for the program, said Ken Johnson, senior vice president of Pharmaceutical Research and Manufacturers of America, an advocacy group for pharmaceutical research and biotechnology companies. But according to the Partnership, more than 29 million might have qualified.

"The real burden is on people who have multiple chronic illnesses who are taking lots of medications," said Arthur Levin, director of the Center for Medical Consumers in New York, a nonprofit patient advocacy group. "They're running up thousands of dollars in drugs costs."

Johnson is covered by a prescription drug plan offered by Medicare, a federal insurance program for those older than 65 and others with disabilities. Her co-pays – or her share of the prescription costs – can run between $6 and $28 a month for each drug, and sometimes more, she said.

She must also cope with the "doughnut hole" in the Medicare prescription program. This quirk cuts off federal coverage for prescription drugs once a patient buys more than an allotted amount of medication in one year, which in 2007 is $2,400. Johnson must spend $3,850 out-of-pocket before coverage kicks back in. With 10 prescriptions, she – like many seniors – anticipates falling into that hole very quickly this year. Last year, the doughnut hole affected about 4 million of the 39 million subscribers to Medicare's drug plan, according to the Kaiser Family Foundation, a nonprofit research group focused on medical issues.

As a result, Johnson said, "you experiment." Some months she stretches out her drug supply by taking less than her prescribed daily dose. Other months, she'll go days without taking a medication, restarting

only when her disease symptoms become unbearable.

It was patients like Johnson who Tarn said inspired her to study the communication between doctors and their charges. As Tarn worked through her residency in family medicine, desperate measures like Johnson's "really made me wonder what we could do better to help our patients, and made me wonder whether better communication could make a difference," she said.

She, along with patient advocacy groups, pharmaceutical and insurance companies have developed strategies to help cut prescription drug costs. But as Tarn's and other numbers show, many struggling patients might not know about them.

For starters, talk to your doctor. Ask what the cost is of any new prescription and if a cheaper alternative is available.

"Doctors are really bad at identifying patients who have problems with cost," Tarn said. But when asked, physicians can often help patients find a less expensive drug with the same benefits. This applies to both insured and uninsured patients; many drug insurance plans offer cheaper co-pays for generic or older brand-name medications.

Make sure you really need all your medications.

Premera Blue Cross of Washington encourages subscribers to carry a brown bag to their doctors' offices holding all vitamins, drugs and other supplements. Go through the contents with your doctor to make sure each one is necessary. A voluntary survey of 11,000 Premera participants showed that 44% received dosage changes and 36% were advised to stop taking at least one existing medication after discussing the drugs with their doctors.

Consider generic drugs. Under federal law, generics must work in the same way and carry the same benefits and risks as their brand-name counterparts. But they often cost significantly less.

Because makers of generic drugs don't have to recoup money spent on creating a drug from scratch, they don't charge as much for the final product.

Although the creator of a drug can usually hold a patent – and thus a monopoly – on a product for 17 years, generic versions are available after the patent expires. The popular antidepressant Zoloft, for example, costs $88.19 for a 30-day supply of 100-milligram tablets on drugstore.com. Its generic equivalent, Sertraline HCl, runs $68.99 for a month's supply at the same strength.

Comparison shop. Prices often vary dramatically by store.

"In a lot of cases, there can be some pretty significant differences between what one pharmacy charges and another," said Ken Johnson, senior vice president of Pharmaceutical Research and Manufacturers of America, an advocacy group for pharmaceutical research and biotechnology companies. For example, Diovan, a popular brand-name blood pressure medication, sells for $90.99 at Walgreens.com for a month's supply of 320-milligram pills.

The same prescription at drugstore.com, which works with Rite Aid pharmacies, costs $83.18. Always make sure an online site requires a prescription, has a pharmacist you can ask questions and is licensed by the state board of pharmacy where it is located. For a list of state boards, visit www.nabp.info.

Split pills. Ask your doctor if your medication can safely be cut in half. If so, a prescription for a double-dose pill might not cost much more than for a single dosage.

At drugstore.com, for example, a month's supply of 160-milligram Diovan pills costs $63.66; customers can buy pills twice as strong for $83.18 per month. For those with insurance, the difference can be an entire co-pay. In 2005, UnitedHealthcare, the nation's second-largest health insurer, issued pill splitters to

subscribers to help them cut drugs and costs. Not all drugs can be split, though, so always check with your physician beforehand.

Make sure a new prescription works for you and doesn't carry harmful side effects before buying a large supply.

Many pharmacies will fill a week's supply if asked when you drop off a new prescription. This trial run will give you a chance to assess the drug's efficacy and potential problems before spending money on something that might not work.

Learn if your insurance plan supports a mail-order pharmacy. If so, you can often order a three-month supply of maintenance drugs at the same co-pay as what one month would cost at the neighborhood drug store.

If you don't have insurance, check out a Patient Assistance Program or drug discount card.

PhRMA will link uninsured patients who earn up to 200% of the federal poverty line – or $41,300 for a family of four – with free or nearly free prescription drugs, Ken Johnson said. The group's website, www.phrma+.org, links patients with a clearinghouse to 475 assistance programs providing 2,500 medications. Since 2005, drug companies have given away $5 billion worth of prescriptions.

If you are uninsured but make too much money to qualify for the assistance programs, ask if your drugstore accepts a discount card. Insured customers won't qualify.

But qualifying uninsured patients can save 25% to 40% on 300 brand name drugs with cards like Together Rx Access, a consortium of 10 pharmaceutical companies that offer medication for diabetes, high blood pressure and depression, among other things. Talk to your pharmacist to see what cards are accepted at your pharmacy and cover your drugs.

Check if your pharmacy offers generic drugs at a flat reduced rate. Both Wal-Mart and Target pharmacies sell hundreds of generic drugs for $4 each for a 30-day supply. Drugs to treat allergies, Parkinson's disease and arthritis are among those included.

Comparison shop before crossing the border.

Although drugs in Mexico and Canada seem cheaper than those in the U.S., consider how much you will spend in travel costs or shipping, and how much you could save by using a discount plan at home. According to the FDA, the savings often are not as high as they might seem.

Karen Abbe/Pharmacy/DCANotes
02/21/2007 02:02 PM

To Virginia Herold/Pharmacy/DCANotes@DCANotes
cc
bcc
Subject press release from Office of National Drug Control Policy: FEDERAL GOVERNMENT ISSUES NEW GUIDELINES FOR PROPER DISPOSAL OF PRESCRIPTION DRUGS

FOR IMMEDIATE RELEASE:
Tuesday, February 20, 2007

CONTACT: Jennifer de Vallance, ONDCP
(202) 395–6648 / (202) 368–8422

FEDERAL GOVERNMENT ISSUES NEW GUIDELINES FOR PROPER DISPOSAL OF PRESCRIPTION DRUGS: WHAT EVERY AMERICAN CAN DO TO PREVENT MISUSE OF PRESCRIPTION DRUGS

(Washington, DC)—In the face of rising trends in prescription drug abuse, the Federal government today issued new guidelines for the proper disposal of unused, unneeded, or expired prescription drugs. The White House Office of National Drug Control Policy (ONDCP), the Department of Health and Human Services (HHS), and the Environmental Protection Agency (EPA) jointly released the new guidelines, which are designed to reduce the diversion of prescription drugs, while also protecting the environment.

The new Federal prescription drug disposal guidelines urge Americans to:

- Take unused, unneeded, or expired prescription drugs out of their original containers
- Mix the prescription drugs with an undesirable substance, like used coffee grounds or kitty litter, and put them in impermeable, non-descript containers, such as empty cans or sealable bags, further ensuring that the drugs are not diverted or accidentally ingested by children or pets
- Throw these containers in the trash
- Flush prescription drugs down the toilet only if the accompanying patient information specifically instructs it is safe to do so
- Return unused, unneeded, or expired prescription drugs to pharmaceutical take-back locations that allow the public to bring unused drugs to a central location for safe disposal

Abuse of prescription drugs to get high has become increasingly prevalent among teens and young adults. Past year abuse of prescription pain killers abuse now ranks second—only behind marijuana—as the Nation's most prevalent illegal drug problem. While overall youth drug use is down by 23 percent since 2001, approximately 6.4 million Americans report non-medical use of prescription drugs. New abusers of prescription drugs have caught up with the number of new users of marijuana. Much of this abuse appears to be fueled by the relative ease of access to prescription drugs. Approximately 60 percent of people who abuse prescription pain killers indicate that they got their prescription drugs from a friend or relative for free.

John Walters, Director of National Drug Control Policy, said, "Millions of Americans benefit from the tremendous scientific achievements represented by modern pharmaceutical products. But, when abused, some prescription drugs can be as addictive and dangerous as illegal street drugs. The new prescription drug disposal guidelines will help us stop and prevent prescription drug abuse, and the harm it can cause.

Health and Human Services Secretary Michael Leavitt said, "Health care providers, pharmacists, and family should be alert to the potential for prescription drug misuse, abuse, and dependence. In addition to supporting the new prescription drug disposal guidelines, they should address prescription drug misuse

honestly and directly with their patients or loved ones when they suspect it. People in need should be encouraged to seek help for drug problems and if needed, enter treatment."

The new Federal guidelines are a balance between public health concerns and potential environmental concerns.

While EPA continues to research the effects of pharmaceuticals in water sources, one thing is clear: improper drug disposal is a prescription for environmental and societal concern," said EPA Administrator Stephen L. Johnson. "Following these new guidelines will protect our Nation's waterways and keep pharmaceuticals out of the hands of potential abusers."

The new Federal prescription drug disposal guidelines go into effect immediately. As part of the National Drug Control Strategy, the Bush Administration has set a goal of reducing prescription drug abuse by 15 percent over three years. In addition to promoting awareness of the risks involved with using prescription drugs for non-medical purposes as well as they need for adults to strictly control access to pharmaceuticals within their homes, the Administration supports the implementation of Prescription Drug Monitoring Programs at the State level. Currently, 33 States have such programs in place.

For more information, please visit www.whitehousedrugpolicy.gov.

Proper Disposal of Prescription Drugs

Office of National Drug Control Policy, February 2007

Federal Guidelines:

- Take unused, unneeded, or expired prescription drugs out of their original containers and throw them in the trash.

- Mixing prescription drugs with an undesirable substance, like used coffee grounds or kitty litter, and putting them in impermeable, non-descript containers, such as empty cans or sealable bags, will further ensure the drugs are not diverted.

- Flush prescription drugs down the toilet *only* if the label specifically instructs doing so.

- Take advantage of community pharmaceutical take-back programs that allow the public to bring unused drugs to a central location for proper disposal. Some communities have pharmaceutical take-back programs or community solid-waste programs that allow the public to bring unused drugs to a central location for proper disposal. Where these exist, they are a good way to dispose of unused pharmeceuticals.

Office of National Drug Control Policy
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Public Ed

Karen Abbe/Pharmacy/DCANotes
02/21/2007 01:20 PM

To Virginia Herold/Pharmacy/DCANotes@DCANotes
cc
bcc
Subject Sacramento Bee: EPA unveils drug disposal guidelines

The Web Site of The Sacramento Bee

EPA unveils drug disposal guidelines

-- The Associated Press
Published 11:01 am PST Wednesday, February 21, 2007

WASHINGTON (AP) Here's a safety tip from your government: Trash those unwanted prescription drugs with kitty litter or coffee grounds to keep them from falling into the wrong hands - and mouths.

New federal prescription drug disposal guidelines recommend mixing unused, unneeded or expired drugs with undesirable substances - like cat litter or coffee grounds - and tossing them in the trash in nondescript containers. Doing so should curb prescription drug abuse and protect lakes and streams from contamination, the White House and government health and environment officials said.

"Following these new guidelines will protect our nation's waterways and keep pharmaceuticals out of the hands of potential abusers," Environmental Protection Agency administrator Stephen L. Johnson said Wednesday.

Drugs should be flushed down the toilet only if the label says it's safe to do so, according to the guidelines. Some pharmacies also collect drugs for safe disposal.

The government warned that abuse of prescription drugs is increasingly common among teens and young adults. Often those drugs are taken from the medicine cabinets of relatives or friends.

While flushing drugs down the toilet can stem that sort of abuse, it also can create environmental problems.

Recent U.S. Geological Survey studies have shown that a wide range of pharmaceuticals and other compounds survive wastewater treatment and later are discharged into lakes, streams and other bodies of water across North America. The USGS research found antidepressants and their byproducts, for example, are being released into the environment at concentrations that may affect aquatic life.

Drug Prices

kaisernetwork.org

Kaiser Daily Health Policy Report

Wednesday, March 07, 2007

Prescription Drugs

Prescription Drug Prices for U.S. Residents Ages 50 and Older Increased at About Twice Inflation Rate, AARP Study Finds

Manufacturers' prices for the 193 prescription drugs most commonly used by U.S. residents ages 50 and older increased at about twice the rate of inflation in 2006, according to an annual report released on Tuesday by AARP, *Cox/Atlanta Journal-Constitution* reports. AARP found that manufacturers' drug prices on average increased by 6.2%, while the Consumer Price Index increased by 3.2%. According to the report, average drug prices since the end of 1999 have increased by nearly 54%, while overall inflation increased by 20% (Lipman, *Cox/Atlanta Journal-Constitution*, 3/7). The report found that the insomnia pill Ambien, manufactured by Sanofi-Aventis, had the highest price increase, up 30% in 2006. Prices for the respiratory drugs Combivent and Atrovent, both manufactured by Boehringer Ingelheim, had the next highest rates of growth, up 18% and 17%, respectively, in 2006, according to the report (*Reuters*, 3/6). David Sloane, senior managing director for government relations and advocacy at AARP, said, "Over time, escalating drug prices will make Medicare drug plans unaffordable for older Americans. One way to address high drug prices is to take full advantage of Medicare's bargaining power and allow Medicare to negotiate lower drug prices" (*Cox/Atlanta Journal-Constitution*, 3/7). He added, "We need to send a loud and clear message to the pharmaceutical industry that Americans cannot afford to continue to pay the highest prices for prescription drugs in the world" (*Reuters*, 3/6).

Industry Response

The pharmaceutical industry called AARP's report "inaccurate and misleading," citing data from CMS and the Bureau of Labor Statistics that show increases in prescription drug spending slowed for the sixth year in a row and retail drug prices increased by 1.5% in 2006. Ken Johnson, vice president of the Pharmaceutical Research and Manufacturers of America, said, "Expert data strongly suggest that AARP's numbers simply do not reflect the true amounts paid by seniors for their medicines. And they do not reflect the clear downward trend in prescription drug price growth" (*Cox/Atlanta Journal-Constitution*, 3/7).

The study is available online. Note: You must have Adobe Acrobat Reader to view the report.

Publicéd

Karen Abbe/Pharmacy/DCANotes
03/08/2007 11:05 AM

To Virginia Herold/Pharmacy/DCANotes@DCANotes
cc
bcc
Subject Associated Press: Drug Imports Battle Heats Up Again

Drug Imports Battle Heats Up Again

The Associated Press
By MATTHEW PERRONE
March 07, 2007

The pharmaceutical lobby pushed back Wednesday against a renewed effort in Congress to pass a law enabling U.S. consumers to buy cheaper prescription drugs from Canada and other countries.

The legislation, supported by Democrats and Republicans, would allow individuals and pharmacies to order drugs from 19 countries. Supporters of the bills point out that Canadians pay about 60 percent less for their medication than Americans, according to a study by the Canadian government.

But the president of the pharmaceutical industry's lobbying group says there are 'better, safer alternatives,' to get affordable drugs to patients.

Billy Tauzin, who formerly chaired a House committee that regulated drug makers and now heads the Pharmaceutical Research and Manufacturers of America, told lawmakers so-called reimportation would expose consumers to counterfeit drugs and force industry to cut back on research and development spending. Tauzin, whose group represents companies such as Pfizer Inc. and Merck & Co., pointed out that the recently launched Medicare prescription drug benefit has greatly increased access to affordable drugs.

Senate Commerce Committee Chairman Daniel Inouye pressed representatives of the medical and legal professions on whether they believe it is fair that Americans pay the highest prices in the world for medications, many of which are produced in the U.S. and affordable at lower prices abroad. Inouye, a Hawaii Democrat, said he plans to move forward with a vote on the measure.

The push to legalize drug imports is not new. Similar legislation has been proposed in Congress since the 1990s without ever passing into law. A 2004 study by the Congressional Budget Office concluded that allowing importation of drugs from foreign countries would reduce total drug spending by about 1 percent over 10 years.

Nevertheless, the issue enjoys widespread support among senior citizen voters. The AARP, which supports the measure, released figures ahead of Wednesday's hearing indicating prices of several key brand name drugs rose at about twice the rate of inflation in 2006.

According to analysts, its unclear how much impact drug reimportation would have on drug company profits. Shares of Pfizer Inc. rose 25 cents Wednesday to $25.44 in mid day trading on the New York Stock Exchange. Merck rose 12 cents to $44.41, also on the NYSE.

Karen
Abbe/Pharmacy/DCANotes
03/12/2007 02:19 PM

To Virginia Herold/Pharmacy/DCANotes@DCANotes
cc
bcc
Subject Washington Post: Internet Offers Many Ways to Avoid Harmful Drug Mixtures

washingtonpost.com

Internet Offers Many Ways to Avoid Harmful Drug Mixtures

Tuesday, February 27, 2007; HE05

To protect against unintended drug interactions, make sure your doctors and pharmacists know "about every drug you are taking, including nonprescription drugs and any dietary supplements such as vitamins, minerals and herbals," the Food and Drug Administration Web site advises.

But that doesn't let you off the hook.

Ultimately, patients bear the onus for keeping tabs of what they take. "It is just vital that patients keep a list of the medications they're taking," said Kasey Thompson, director of patient safety at the American Society of Health-System Pharmacists.

Armed with that list, patients can call their doctor or pharmacist to ask whether it's safe to add a product. They can also do their own homework and -- as a first step -- check online for potential drug interactions. But because the alerts listed may be incomplete or not specific to your needs, it's smart to check that information with your doctor or pharmacist. Here are some free (with the exception of one site, as noted) online resources that may be useful:

Medication Information

American Pharmacists Association , drug information site, http://www.pharmacist.com/drug_information.cfm

American Society of Health-System Pharmacists , which offers tips and advice for using medications safely and effectively, http://www.safemedication.com

As You Age: A Guide to Aging, Medicines and Alcohol , U.S. Department of Health and Human Services, http://www.asyouage.samhsa.gov/media/asyouage/asyouagebrochure01.pdf

Consumer Reports Guides to Prescription, OTC and Natural Medicines , http://www.consumerreports.org/mg/a-z-drug-index/A.htm and http://www.consumerreports.org/mg/natural-medicine/index.htm (Note: Some pages on the Consumer Reports site require a paid subscription.)

Drug Interactions: What you should know , FDA,

http://www.fda.gov/cder/consumerinfo/druginte3.pdf

Drugs@FDA , a database offering detailed information about all drugs approved by the FDA, http://www.accessdata.fda.gov/scripts/cder/drugsatfda

Be an Active Member of Your Health Care Team , an FDA presentation, http://www.fda.gov/cder/consumerinfo/Be-An-Active-Member-2005.pdf

My Medicines , a form for listing your medications and supplements, http://www.fda.gov/cder/consumerinfo/mymeds.pdf

Herb and Drug Interactions , Mayo Clinic, http://www.mayoclinic.com/health/herbal-supplements/SA00039

Your Medicine: Play It Safe , Agency for Healthcare Research and Quality, http://www.ahrq.gov/consumer/safemeds/safemeds.htm

Drug Interaction Checkers

About.com List , http://www.thyroid.about.com/library/drugs/blinteractionchecker.htm

Caremark , http://www.caremark.com; click on Drug Interactions under the heading Health Resources

Discovery Health , http://www.health.discovery.com; search for "drug interaction"

Drugs.com , http://www.drugs.com/drug_interactions.html

Drugstore.com , http://www.drugstore.com/pharmacy/drugchecker

Eckerd , http://www.eckerd.com; click on Pharmacy, then select Drug Interaction Tool

Express Scripts , http://www.drugdigest.org; click on Check Interactions

Medscape , http://www.medscape.com; search for "drug interaction checker"

University of Maryland Medical Center , http://www.umm.edu/adam/drug_checker.htm

Walgreens , http://www.walgreens.com/help/hy_cdi.jsp (Requires free site registration.)

Wal-Mart , http://www.walmart.com/pharmacy; click on Learn About Drug Interactions under heading Health & Drug Information

-- January W. Payne

Karen Abbe/Pharmacy/DCANotes
03/15/2007 08:12 AM

To Virginia Herold/Pharmacy/DCANotes@DCANotes
cc
bcc
Subject Sacramento Bee: Medicine that talks

The Web Site of The Sacramento Bee

Medicine that talks

By LEE BOWMAN -- Scripps Howard News Service
Published 12:35 pm PDT Wednesday, March 14, 2007

Time to take your pill.

You know it is because your cell phone or other hand-held electronic device just issued you a reminder in a text or voice message. Or maybe an alarm set on the cap of your medicine bottle chirped, re-setting for the next dose as you replace the cap.

A while later, as the pill makes its way through the digestive system and dissolves, a tiny radio chip attached to it emits a weak signal that's recorded by a pager-sized sensor on your belt, documenting that the medicinal mission was accomplished.

The device may go on sending a wireless signal to your doctor or nurse, and may even update your Web-based electronic medical record.

If this all seems a bit of futuristic excess to ensure drug compliance, rest assured that all these technologies already exist and most are commercially available.

And the nagging may be needed. Studies indicate that only half to perhaps as few as a third of seniors take prescriptions as they're supposed to all the time.

The solution may be as simple as the "Beep N Tell" medication reminder cap that plays a voice recording from the patient or a caregiver that can go off as many as 24 times a day; or as complex as Medsignals, which features both the alerts and automatically passes on data to a computer database.

Some of the innovations require more active participation. At a recent conference on "mobile persuasion" techniques held at Stanford University, a company called myFoodPhone Nutrition presented its service designed for camera phones.

Users take a picture of their plate at each meal and build an online food journal. A team of nutrition coaches and advisers analyzes the meals weekly and provides online counseling about what might be changed.

Downloading what you're eating is one thing, but one of the big sticking points for tracking drug intake is the still-garbled world of electronic medical records. Industries are still wrangling over standard formats for medical information, but a bigger problem is being able to ensure that all the health care a person receives is logged in, and that everyone who should be able to access the information can do so, but no one else.

Health insurers and a host of private services are establishing personal health record sites with password protection and other safeguards, and surveys show most patients like the idea of being able to access their personal health records.

But polls also show they're anxious about who else might peek, and there are thorny intergenerational issues about whether adult children caring for elderly parents should have full access, or parents of adolescents.

Still, there's evidence that a little tattling about what you're taking can help.

For instance, in Wyoming, an information management system called RiteTrack is used to follow how supplies of nicotine gum or lozenges are dispensed for each client in the Wyoming Quit Tobacco Program.

People in the program get vouchers to help pay for the drugs but must also enroll in a telephone counseling program. The counselors use data about the quantity of gum and lozenges the smoker's been getting to help guide them in kicking the habit. Studies have shown that tele-counseling can double a person's chances of quitting over using self-help material alone; and nicotine replacement therapies double the odds yet again.

As far as tattletale pills go, they're the next generation of pills and devices that are already used by doctors to take various images of our innards.

Kodak filed a patent on the radio-frequency technology last month, but company officials didn't outline any timetable for bringing out a commercial product.

On the Net: http://www.nia.nih.gov

Public Ed

Karen Abbe/Pharmacy/DCANotes
01/16/2007 08:09 AM

To Virginia Herold/Pharmacy/DCANotes@DCANotes
cc
bcc
Subject USA Today: FDA to sweep unapproved drugs off the market

Page 8D

FDA to sweep unapproved drugs off the market

Unknown whether 2% are safe, effective

By Rita Rubin
USA TODAY

ROCKVILLE, Md. – A Food and Drug Administration official told representatives of 65 companies that sell unapproved drugs Tuesday that the agency plans to step up efforts to remove such products from the market.

"We do intend to accelerate removal of unapproved drugs this year," Deborah Autor, director of the FDA's Office of Compliance, said at a day-long workshop about the routes that manufacturers of unapproved drugs can take to get the agency's blessing and avoid expulsion from the market.

In September, a USA TODAY cover story reported that many doctors, patients and pharmacists were unaware that some medications on the market – nearly 2% of prescription drugs, according to the FDA – have never been scrutinized by the agency.

The story spurred Sen. Chuck Grassley, R-Iowa, to write a letter to FDA Commissioner Andrew von Eschenbach asking for more information about how unapproved drugs end up on the market.

The medications are sold as prescription and over-the-counter products for a range of ailments, including colds and coughs, hot flashes and pain. But consumers cannot be sure whether such medications are effective, let alone safe, Autor says.

Companies that market unapproved drugs, many of which have been sold for years, argue that their products have stood the test of time. But, said Robert Temple, director of the FDA's Office of Medical Policy, "the fact that there's long-term use really doesn't tell you anything."

Temple cited the case of anticholinergic sedatives, which had been used for years to treat irritable bowel syndrome. Eventually, the drugs were tested for that condition in large clinical trials, Temple said, and "every one of them failed completely."

When one audience member asked why the FDA doesn't just ban all unapproved drugs, Autor said the agency instead is taking a "concerted and concentrated approach." She said, "We are constantly evaluating potential targets."

One priority is getting unapproved versions of approved drugs off the market, Autor said.

URL/Mutual Pharmaceuticals of Philadelphia waited nearly a year for the FDA to remove unapproved quinine products from the market before launching Qualaquin, its approved version of the drug, in July. Qualaquin is prescribed for malaria, but the unapproved versions were marketed for leg cramps and other uses as well as malaria.

URL filed court motions in August against seven makers of unapproved quinine sulfate products, and all but one agreed to stop selling them by mid-November. Finally, the FDA announced last month that, because of safety concerns, it had ordered all unapproved quinine products off the market. Since 1969, the FDA said, unapproved quinine products had been linked to 93 deaths.

FDA NEWS

THE FOOD AND DRUG ADMINISTRATION / AN AGENCY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public

EMBARGOED UNTIL 1:00 p.m. EST

FOR IMMEDIATE RELEASE
January 11, 2007
P07-03

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FDA Proposes New Measures to Strengthen Drug Safety Under PDUFA Reauthorized User Fee Program

Proposed Recommendations Would Also Enhance Drug Development, Boost Reviews of TV Drug Commercials

The Food and Drug Administration (FDA) today proposed recommendations to Congress for the next reauthorization of the Prescription Drug User Fee program which, if adopted, would significantly broaden and upgrade the agency's drug safety program, increase resources for review of television drug advertising, and facilitate more efficient development of safe and effective new medications for the American public. To achieve these public health benefits, the agency proposes to recommend, as part of the reauthorization of the program, that annual user fee collections be increased to $392.8 million, an $87.4 million increase over the current base line.

The user fee program, which was first authorized by the Prescription Drug Use Fee Act (PDUFA) in November 1992, adds industry's funds to the agency's appropriations to help FDA's human drug review program achieve demanding performance goals. Over the years, the PDUFA programs, which have to be reauthorized by Congress every five years, have enabled the agency to dramatically reduce its review times for drugs and biological medications while increasing scientific consultations, clarifying issues involving drug development, and increasing oversight of postmarket safety.

"The proposed recommendations would support significant improvements in FDA's ability to monitor and respond to emerging drug safety issues, as well as continuing FDA's commitment to scientific improvements to and streamlining the drug approval process," said HHS Secretary Mike Leavitt. "I commend FDA for the important progress they have made and look forward to working with Congress to ensure action on these proposals."

"In the last 14 years, three consecutive user fee programs -- PDUFA I, II and III -- have brought enormous public health gains to our and, indeed, the world's consumers, by helping FDA make increasingly complex medications available to patients faster than was ever possible before without sacrificing quality," said Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs. "Our proposed recommendations for PDUFA IV aim to top these accomplishments by achieving, above all, an impressive expansion and modernization of our drug safety system, and adding resources to enhance information technology initiatives."

To develop the proposal, FDA held a public meeting and other consultations with stakeholders, including organizations representing health care professionals, consumers, patient advocates,

and regulated industry. These stakeholders urged the FDA to seek additional appropriated funds to strengthen its ongoing drug safety program. In addition, consumer groups favored the adoption of user fees to increase FDA's capacity for review of direct-to-consumer TV ads.

Based on these consultations and an analysis of its commitments and anticipated means, FDA proposes to recommend using the $87.4 million user fee increase for significant program enhancements. PDUFA IV is the mechanism for placing the drug review process on a sound financial footing. The following are the key components of the proposal:

Program enhancements: $37.9 million
The biggest recommended increase, of $29.3 million, would provide a major boost for FDA activities to ensure the safety of medications after they are on the market. The increased funds would be available for FDA drug safety activities for marketed medications throughout as long as they remain on the market and would increase FDA's drug safety capacity for surveillance including hiring an additional 82 employees to perform postmarket safety work. To that end, FDA also recommends elimination of a statutory provision under which PDUFA fees may be used to assess safety issues only during the first three years after the product's approval. The agency would also use the added resources to adopt new scientific approaches and improve the utility of existing tools for the detection and prevention of adverse events, for example obtaining access to the best available databases to better analyze drug safety signals.

Other enhancement proposals call for:
*$4.6 million in new user fees and 20 employees to help expand FDA's implementation of guidance for FDA's reviewers (Good Review Management Principles) and develop guidelines for industry on clinical trial designs and other topics; and
*additional $4 million to improve the information technology activities for human drug review by moving the agency and industry towards an all-electronic environment.

In addition, the FDA proposes to recommend creating a separate new user fee program to collect new fees from companies that seek FDA advisory reviews of their direct-to-consumer television advertisements. FDA anticipates that these fees will be $6.2 million in the first year and support 27 additional staff to carry out this review function.

Financial baseline: $49.4 million

Since the user fees collected have not kept up with the increasing costs of the program, FDA proposes to request several increases in user fees to stabilize PDUFA IV's financial base line, to be divided as follows:
*$17.7 million to adjust the base amount for inflation and support increases in salaries and benefits;
*$11.7 to ensure that the fees cover a share of increased rents and the costs of the agency's move to the new White Oak facility in Silver Spring, Md.;
*$20 million in additional fees to cover significant increases in FDA's drug review workload that were incurred but not compensated for under PDUFA III, and are expected to continue.

FDA's PDUFA proposals will be presented to the public at a public meeting on February 16, 2007. After all public comments are evaluated and any appropriate changes made, final proposals will be submitted to Congress. PDUFA reauthorization would go into effect only after enacted by Congress and signed by the President.

For more information, The Federal Register Notice is available at
http://www.accessdata.fda.gov/scripts/oc/ohrms/advdisplay.cfm

FDA's PDUFA proposals will be presented to the public at a public meeting on February 16, 2007. After all public comments are evaluated and any appropriate changes made, final proposals will be submitted to Congress.

To submit electronic comments on the documents, visit http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm?AGENCY=FDA. Written comments may be sent to: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD, 20852. Comments must be received by Feb. 23, 2007 and should include the docket number 2007N-0005.

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ATTENTION TV BROADCASTERS: Please use open caption for the hearing impaired.

FDA On The Internet: www.fda.gov

Karen Abbe/Pharmacy/DCANotes
03/15/2007 10:13 AM

To Virginia Herold/Pharmacy/DCANotes@DCANotes
cc
bcc
Subject USA Today: College drug use, binge drinking rise Prescription abuse, pot use both way up

USA TODAY

College drug use, binge drinking rise Prescription abuse, pot use both way up

By Donna Leinwand, USA TODAY

Nearly half of America's 5.4 million full-time college students abuse drugs or drink alcohol on binges at least once a month, according to a new study that portrays substance and alcohol abuse as an increasingly urgent problem on campuses across the nation.

Alcohol remains the favored substance of abuse on college campuses by far, but the abuse of prescription drugs and marijuana has increased dramatically since the mid-1990s, according to the study released today by the National Center on Addiction and Substance Abuse (CASA) at Columbia University.

CASA, which called on educators to move more aggressively to counter intensifying drug and alcohol use among students, first studied students' drug and alcohol habits in 1993. Today's report – the center's second on the subject – involved a survey of 2,000 student and 400 administrators as well as analyses of six national studies.

The center found that "the situation on America's campuses has deteriorated" since 1993, CASA President Joseph Califano says.

'HIGHER' EDUCATION?

The percentage of college students saying they took potentially dangerous drugs during the previous year is up:

Any illicit drug
- 1993: 30.6
- 2005: 36.6

Marijuana
- 1993: 27.9
- 2005: 33.3

Hallucinogens
- 1993: 6.0
- 2005: 5.0

Inhalants
- 1993: 3.8
- 2005: 1.8

Cocaine
- 1993: 2.7

• 2005: 5.7

Heroin
• 1993: 0.1
• 2005: 0.3

Source: The National Center on Addiction and Substance Abuse at Columbia University

AUDIO: Califano: Time to get the 'high' out of higher education

The study found that college students have higher rates of alcohol or drug addiction than the general public: 22.9% of students meet the medical definition for alcohol or drug abuse or dependence – a compulsive use of a substance despite negative consequences – compared with 8.5% of all people 12 and older.

White students are more likely to use drugs and alcohol than minority students, and students at historically black colleges have much lower rates of substance abuse than other students, the study found.

School administrators have not done enough to curtail drug and alcohol abuse on campus, Califano says. In CASA's survey of administrators, two-thirds said responsibility for stopping drug abuse rests with students.

"It's not on the radar screen of college presidents. This is not a priority," Califano says. "We believe they have an obligation to protect the health and safety of their students."

Donald Harward, president emeritus of Bates College in Maine, says drinking and drug abuse are a symptom of students' disengagement from academic and civil life on campus. "I think a lot of presidents are aware of (increasing alcohol and drug problems among students), and they are struggling to come to grips with it."

Nearly half the students surveyed by CASA said they drank or used drugs to relax, reduce stress or forget about problems. Other findings:

Students who said they had abused painkillers such as Percocet, Vicodin and OxyContin during the past month rose from fewer than 1% of students in 1993 to 3.1% in 2005, a reflection of how the rising number and availability of prescription drugs has increased abuse.

The percentage of students who reported smoking marijuana heavily – at least 20 days during the past month – more than doubled, from 1.9% in 1993 to 4% in 2005.

The percentage of students who reported using illegal drugs other than marijuana, such as cocaine and heroin, in the past month jumped from 5.4% in 1993 to 8.2% in 2005.

Overall, the percentage of students who reported drinking alcohol at least occasionally was about the same: 68% in 2005, compared with 70% in 1993. Those who said they engaged in binge drinking – defined as having five drinks for male students and four drinks for female students at one "drinking occasion" during the previous two weeks – held steady at 40%.

However, the percentage of students who reported binge drinking three or more times during the previous two weeks increased from 19.7% in 1993 to 22.8% in 2001, the study found. In 2005, 83% of campus arrests involved alcohol, the study found.

Attachment A

Meeting Summary of the Communication and Public Education Committee Meeting of April 3, 2007

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE MEETING SUMMARY

Date:	April 3, 2007
Location:	Department of Consumer Affairs First Floor Hearing Room 1625 N. Market Boulevard Sacramento, CA 95834
Board Members Present:	Ken Schell, PharmD, Board Member and Chairperson Henry Hough, Board Member
Board Members Absent:	Bill Powers, Board President Andrea Zinder, Board Member
Staff Present:	Virginia Herold, Executive Officer Anne Sodergren, Legislation and Regulation Manager Karen Abbe, Public and Licensee Education Analyst

Call to Order

Chairperson Schell called the meeting to order at 1:48 p.m.

1. Discussion About the Practice of Pill Splitting

During the Subcommittee on Medicare Drug Benefit Plans on November 30, 2006, the committee was asked to consider the safety of pill splitting by patients. Charles Phillips, M.D., attended the subcommittee meeting and stated that he was concerned with the practice of pill splitting due to pills not splitting evenly resulting in uneven dosing, and the resultant crumbled residue of drug product in the bottom of pill containers.

Subcommittee Chairperson Goldenberg asked Dr. Phillips to provide information on this topic at a future board meeting. Dr. Phillips subsequently attended the board meeting held on January 31, 2007, and provided his testimony against the practice of pill splitting. Several other speakers provided their comments in support of pill splitting.

The board referred the matter to (both) the Communication and Public Education Committee and the Legislation and Regulation Committee for further discussion. The meeting materials packet for this meeting included the following attachments from the January 31, 2007 Board Meeting:

From BOP

1. Excerpts from the (draft) minutes regarding the discussion on pill splitting

From Dr. Charles Phillips

- NABP 2nd Quarter 2000 newsletter containing an article entitled "Tablet-Splitting Policies Raise Concern"
- NABP Resolution No. 97-4-01 entitled "Opposition to Mandated Tablet Splitting"
- Numerous additional articles, labeled in the packet as "con"

From Dr. John Jones (United Health Care)

- Frequently Asked Questions from United Health Care entitled "Half Tablet Program – Effective August 15, 2006"

From Dr. Steven Gray (Kaiser Permanente)

- Various news articles and scientific research on the subject of pill splitting, including an article from Consumer Reports, labeled as "pro"

Dr. Schell stated that the Legislation and Regulation Committee met earlier in the day, but the meeting was truncated due to time constraints. Dr. Phillips provided comments during the Legislation and Regulation Committee meeting, and Dr. Schell opened the floor to carry on the discussion regarding pill splitting.

Dr. Schell stated that he wants the audience to bring suggestions to the committee on how best to serve the public in educating people on the issue of pill splitting. He stated that Dr. Phillips provided a wealth of information at the January 2007 Board meeting, and he called on him to make additional comments and suggestions.

Dr. Phillips stated that the committee was gracious to arrange this forum. He referred to the notebooks he provided earlier in the day. Each notebook contained a cover letter to each committee (Legislation & Regulation, and Communication & Public Education), as well as articles and other supporting documentation.

He stated that on the theory the board would not take instant action on this issue, he drafted "informed consent" language. The informed consent language encompasses items #1 - #6 in his cover letter to each committee. Items #6 - #10 provide other

information to regarding pill splitting. The 10 items and two footnotes are shown below (without modifications or alterations to the spelling or content provided by Dr. Phillips).

1. Your prescription has the option of being filled by pills that are split into usually unequal pieces for the saving of health system moneys; you have a right to know where this money goes since you are taking on the disease risk of uneven dosing[12].

2. after reading all of these notes you can chose to have the split of the double size pill approach or the unsplit whole pill without any pressure, influence, criticism, fear of reprisal, or thought that your caregiver might even be annoyed (in case he or she is tracked for pharmacy costs of his or her patients);

3. The research on this topic involved patients who split their pills every day and took the large and small fragments within two days, thus balancing out the dosage; these were on pills that stick around a long time so it has been presumed safe.

4. If you are being asked to split pills in large numbers all at once, there is no research to say that is safe and, in fact, it would be most likely unsafe[13]; bouncing cholesterol, blood pressure, diabetes, etc. has no likelihood of being safe and is most likely to accelerate your disease process;

5. The most common problem surfacing in pill splitting – as discovered by NASA in the contract review of VA practices – is the doubling of pills, and this commonly occurs to about 9% of the splitters about three times a month; your physician and pharmacist need to be sure that a double dose is safe for you on occasion (too tired to split a pill some sleepy morning);

6. There is also no science that says that if you split 200 days of medication that the exposed surfaces of the pills will not add oxygen or water in a way that changes their effect, since pill splitting was never part of the animal or human studies on the way to this after sale practice of dispensing; there have been warnings about this;

7. The newest pill splitters – which you need to request – have child safety plastics that prevent fingers from being cut; but no splitter is child proof to be opened so that any pills or fragments left in the pill splitter can be of harm to your children, grandchildren, or young visitors.

8. You need to replace the one or several pill fragments back into your pill bottle but be able to find them before they migrate down to the bottom; ask your pharmacist how to do this safely;

9. The average time calculated in the US and Canada for safe counseling on pill splitters by pharmacy students or pharmacists is considerable[14]; expect that counseling to be needed on the first few refills and twice a year so that you do not fall into several common error patterns;

10. The California Board of Pharmacy would like to hear about any errors that occur in pill splitting is this largest of states at phone number 916-___-____.

[12] This would be the place where an HMO could explain the vast savings that accrue and the split of profits with the physicians. Perhaps the accumulation of $1 billion by CEO Dr. William Mc Guire while making these decisions might suggest that his decisions involved a hand in the cookie jar. I once tried to talk him out of pill splitting; but he continued undaunted.

[13] Note Kaiser has offered up no research of its own, although a surprising number of investigators on this topic have ended up Kaiser-financed-related before the day of publication – two pharmacists and one "pharmaco-economist." It is unclear to me whether or not Dr. Stafford, the pharmaco-economist – who did not study safety in pill splitting beyond the theoretical – ever gave out one pill in his life. His supposed ties to Harvard, Yale, and Stanford did not seem to change the practice – almost no pill splitting – of any of them.

Dr. Schell thanked Dr. Phillips for his presentation, and stated that we have a tremendous opportunity to educate the public on this issue. He recommended that the board do two things:

1. Distribute a document related to myths and facts about pill splitting, providing substance to the public so they will have the information necessary to make decisions

2. Look at the clinical impact of pill splitting to see if harm is done to patients, and whether patients remain stable (based on clinical outcomes)

Mr. Hough said this issue falls under consumer protection, and he considers this part of his continuing education. He said the information is interesting and astounding, and something that the board should consider and publicize.

Sandra Bauer introduced herself as a former board member. She said that the issue of pill splitting is relevant, but focusing on cost sends the wrong signal. Pill splitting goes down the wrong road, and it's complicated. It's not a safe practice. Ms. Bauer asked that the board say that pill splitting is a bad practice.

Dr. Schell asked about pricing strategies and why different dosages of the same medication can be priced the same.

Dr. Phillips stated that came as a result of the pharmaceutical industry in 1992 when they started "flat pricing."

Dr. Schell asked if there were any other comments on the issue. There were none.

2. Consumer Fact Sheet Series with UCSF's Center for Consumer Self Care

Three years ago, the board approved a proposal by the committee to integrate pharmacy students into public outreach activities. The project involves UCSF students developing one-page fact sheets on diverse health care topics for public education.

An important objective of the fact sheets was to develop new educational materials for issues that emerge in the health care area and for which there is no or little written consumer information available. This would aid the interns who develop the materials and gain the experience of developing consumer informational materials. It also benefits the board, because it gains an invigorated set of public informational materials that are topical and not generally available.

The UCSF's Center for Consumer Self Care works directly with the students to develop the fact sheets, which are then reviewed by faculty members and then by the board. The board distributes these fact sheets at community health fairs and has them available online. The fact sheet format is intended to be attractive whether printed or photocopied.

So far, nine fact sheets have been developed in the first year. These fact sheets have been translated by the board into Spanish, Vietnamese and Chinese, and are available on the board's Web site.

Bill Soller, PhD, of the UCSF Center for Consumer Self Care is overseeing this project. At the September 2006 committee meeting, Dr. Soller provided four new fact sheets. The committee recommended changes, which were provided to Dr. Soller. In January the board's new consumer outreach analyst Karen Abbe noted several additional changes that need to be made to the fact sheets.

Dr. Soller attended this meeting and distributed the following fact sheets:

- Falls - with emphasis on medicines that put you at risk - talk to your pharmacist/read the label
- Consumer reporting of adverse drug events - based on FDA quote, "Consumers can play an important public health role by reporting to FDA any adverse reactions or other problems with products the Agency regulates. When problems with FDA-regulated products occur, the Agency wants to know about them and has several ways for the public to make reports. Timely reporting by consumers, health professionals, and FDA-regulated companies allows the Agency to take prompt action. FDA evaluates the reports to determine how serious the problem is, and if necessary, may request additional information from the person who filed the report before taking action."
- Driving when you are taking medicines
- Tips for Parents - read the label (teaspoons and tablespoons, more is not better, ask your pharmacist)
- Allergies to medicines - what to look for, what to do before purchase, read label/ask your pharmacist, consumer reports to MedWatch current listing on Web site

Topics Suggested for Consumer Fact Sheet Series

1. Different dosage form of drugs -- the ability for patients to request a specific type of product (liquid or capsule) that would best fit the patients' needs for a given type of medication. Also differences between tablespoons, mLs, cc, teaspoon measures.
2. Falls - with emphasis on medicines that put you at risk - talk to your pharmacist/read the label

3. Consumer reporting of adverse drug events -- based on FDA quote, "Consumers can play an important public health role by reporting to FDA any adverse reactions or other problems with products the Agency regulates. When problems with FDA-regulated products occur, the Agency wants to know about them and has several ways for the public to make reports. Timely reporting by consumers, health professionals, and FDA-regulated companies allows the Agency to take prompt action. FDA evaluates the reports to determine how serious the problem is, and if necessary, may request additional information from the person who filed the report before taking action."
4. Driving when you are taking medicines
5. Rebound headaches and the danger of taking too many OTC pain relievers for headaches
6. Hormone replacement therapy -- what is the current thinking?
7. Pediatric issues
8. Poison control issues
9. Ask for drug product information and labels in your native language if you cannot read English
10. Cough and cold meds and addiction issues (specifically, dextromethorophan)
11. Taking your Medicines Right (four fact sheets)
    - How to Use an Rx Label
    - How to Use an OTC Label
    - How to Use a Dietary Supplement Label
    - How to Use a Food Label
12. Take Only as Directed (three fact sheets)
    - Dangers of Double Dosing
    - Disposal of Out of Date Medicines
    - Tips on How to Take your Medicine Safely
13. Ask your Pharmacist or Doctor
    - Have a question?
    - Ask your Pharmacist for Native Language Materials/Labeling
14. Questions to Ask About your Condition or Medicine:
    - Diabetes: Questions to Ask
    - Cardiovascular Disease: Questions to Ask
    - Asthma: Questions to Ask
    - Depression: Questions to Ask
    - Arthritis and Pain: Questions to Ask
15. What Can I do to Prevent Disease?
    - Regular Check Ups
    - Screening
    - What Medicare Offers
16. Childhood Illnesses and Conditions
    - Head Lice
    - Fever Reducers: Questions to Ask
    - Immunizations: Questions to Ask & Schedules
17. Questions to Ask About Your Medicines
    - What Are Drug Interactions?

- Ask Your Pharmacist: Medicare Part D Prescription Drug Benefit
- Medication Therapy Management – What Is It?
- Drinking and Taking Medicines

18. Learn More about your Medicine
    - Credible Sources on the Internet

Medicine Safety

- Heading: Read the Label
  - "How to Read an Rx Label"
  - "How to Use an OTC Label"
  - "How to Use a Dietary Supplement Label"
  - "How to Use a Food Label"
- "A Medicine Chest for Traveling"
- "Drug-Drug Interactions"

Health Topics

- "Diabetes and Aspirin"
- "Asthma – Safe Use of Inhalers"
- "Immunizations"
- "Checking Your Blood Pressure"
- "Head Lice – Back to School"

Tips for Parents

- read the label
- teaspoons and tablespoons
- more is not better
- ask your pharmacist

Aspirin for Heart Attack and Stroke

- aspirin is not for everyone
- risks associated with aspirin
- what to think about before starting daily aspirin

Counterfeit Medicines

- dangers of using counterfeit medicines
- what to look for
- ask your pharmacist

Consumer Drug information on the Internet

- how to judge reliable information
- sites to trust
- where to look
- ask your pharmacist

Allergies to Medicines

- what to look for

- what to do
- before purchase, read the label – inactive ingredient section
- consumer reports to FDA (MedWatch)
- ask your pharmacist

Immunizations

- immunization schedules
- what schools require
- awareness alert that some pharmacies provide immunization services
- ask your pharmacist

Dr. Soller said that the best way to pursue the fact sheets is to have them be developed in an ongoing fashion. He recommended that as issues arise such as pill splitting, a new fact sheet can be put out.

Dr. Soller stated that he has used grounded theory in the fact sheets, and used specific consumer language that a consumer would use. He provided color copies of four fact sheets for consideration by the committee. He recommended a conference call with staff to be sure that final editing is in place.

Dr. Schell asked about citations previously requested on the "An aspirin a day?" and "Medication Errors" fact sheets.

Dr. Soller responded that the problem is space and type size. He maintains references and is sure they are current.

Ms. Herold clarified that the board requested the citations for annotation purposes, not necessarily to be placed on the actual fact sheets for consumers. In the event the board is queried about references, we can show we've done due diligence.

Dr. Soller responded that he would provide annotated copies for the board. He then provided background information on some of the new fact sheets he presented.

The fact sheet entitled "Preventing Falls" came up by a resident who was on the NIH Web site. A portion of the site was devoted to what medications can cause falls. Dr. Soller believes the fact sheet developed presents the information in a more readable format.

The fact sheet entitled "Is the site reliable?" was taken from information from the FDA. It was not put into a sixth grade reading level because it is more oriented to web savvy consumers. The FDA prepared this fact sheet through a web quality survey, and collectively put the recommendations together. Borrowing this information would make FDA a partner in the fact sheets.

The fact sheet entitled "Your Right as a patient and consumer of healthcare" came from the Board of Pharmacy's Web site. Dr. Soller stated that his student copied the

information from the board's Web site. Dr. Soller said that he didn't know until later that the information was gleaned from the board's Web site. He recommends that the information be reworked and condensed, and will be revised.

Mr. Hough asked about studies that show that seniors do not take their medications as directed. He stated that he's been taking blood pressure medication since 1981, and he is systematic about it.

Dr. Soller stated that rough figures show that 50% of patients are not "adherent to medications" after one year of taking meds. He wants to find funding to promote adherence to medications, and he's looked into that. He agrees that it's a good issue to get behind.

Fred Mayer, R.Ph., M.P.H., President of Pharmacists Planning Service, Inc. (PPSI), introduced himself and said he wants to ask for a brochure on acetaminophen or Tylenol.

Dr. Soller replied that there was already a fact sheet on this topic produced in this fact sheet series: "What's the deal with double dosing – Acetaminophen, that's what." He suggested that it would be appropriate to take ideas on how to improve the message.

Sandra Bauer stated that it is important to create a "brand" so that all publications are identifiable as board materials. She would like to see the board's logo with the mortar and pedestal at the top of every publication.

Dr. Soller stated that the board logo and phrase is shown on each fact sheet, though not at the top.

Ms. Bauer stated that the board used to have the same color and logo on all brochures (i.e., Health Notes) and hammered down the "Be Aware and Take Care, Talk to Your Pharmacist" slogan. She suggested that the board cannot state this too many times.

Ms. Herold clarified that the board does maintain "branding." With the newly revised fact sheets, we will have 15 consumer fact sheets. They are accessible and downloadable on the board's Web site, and user friendly. They are distributed by the board and Department of Consumer Affairs at health fairs, available on the board's Web site, and have been promoted to pharmacists for downloading to patients in the board's newsletter.

Ms. Bauer suggested that the web addresses for the actual fact sheets be placed on the fact sheets so that people can readily download extra copies. The board's Web address is a start, but the actual Web page for each fact sheet would be more helpful.

Ms. Herold said the board will add the link to our Web page that lists the publications. From that page, consumers can link to all the fact sheets.

Ms. Herold stated that she had been approached by two interns from other schools of pharmacy who are interested in developing fact sheets for this project. She suggested that if two people came to her, there are probably other students that are interested in working on this project as well. She asked Dr. Soller how we can we expand this beyond just UCSF.

Dr. Soller replied that it could work, and he wouldn't have a problem working with other students.

Ms. Herold responded that she will provide these students with Dr. Soller's contact information. There are 30-40 topics in the potential "hopper" that could be addressed.

Dr. Schell thanked everyone for the comments regarding the consumer fact sheets.

3. Update on the Activities of the California Health Communication Partnership

Dr. Schell stated that the board is a founding member of the California Health Communication Partnership. This group is spearheaded by the UCSF's Center for Consumer Self Care to improve the health of Californians by developing and promoting consumer health education programs and activities developed by the members in an integrated fashion.

There have been three major campaigns since the formation of the group about three years ago. The last campaign ended in the fall of 2006, and was the second year of the cancer screening campaign, which aimed at educating the public about the need for an importance of breast cancer or prostate cancer screening. The campaign was titled: "It's Your Life, Do it Today." Outside funding from a private foundation enabled the use of a vendor that specializes in distributing prewritten consumer columns for small and typically weekly newspapers. There were also public service announcements intended for airing on radio. This great expands the exposure and reach of the campaign.

Dr. Soller stated that the California Health Communication Partnership completed two campaigns for breast cancer screening and two on prostate cancer screening. The campaigns won awards and he is still receiving trickling reports on how the information is being published. He said the message is out to a lot of people.

He added that it is a struggle to find that outside group that would fund medication adherence or a similar campaign, for example on generics.

Dr. Schell asked if there were any comments or questions regarding the Partnership. There were none. He thanked Dr. Soller for his presentations.

4. Update Report of The Script

The next issue of *The Script* is planned for publication and distribution in July 2007. The focus of that issue will be on application of laws, and questions and answers about pharmacy practice asked of the board.

5. Development of New Consumer Brochures

Dr. Schell stated that Consumer Outreach Analyst Karen Abbe has initiated work on building and revising some of the board's public education materials.

In draft manuscript form in the committee's packet are:

- *Board of Pharmacy Informational Brochures*

  Ms. Abbe has revised two brochures about the board. One draft is an overview of the board, and the other is information about filing a complaint with the board. The manuscripts will be converted into publications by the next meeting.

Currently under development are:

- *Prescription Drug Discount Program for Medicare Recipients*

  The board has started revision of the "Prescription Drug Discount Program for Medicare Recipients" brochure that was developed in response to SB 393 (Speier, Chapter 946, Statutes of 1999). This state program allows Medicare recipients to obtain medications at the MediCal price if the patients pay out of pocket for the medication. The brochure needs to be meshed with the Medicare Part D Plan benefits that became available to beneficiaries in 2006.

- *Informational Fact Sheets for Applicants*

  The board produces detailed instructions for applicants for the pharmacist examination, however, some applicants do not read this information or retain it.

  To improve the application process, the board will soon develop specialized fact sheets on:

  - Information about applying for the CPJE or a California intern pharmacist license specifically for pharmacists licensed in other states
  - Information about how foreign graduates can qualify for a pharmacist license in California

- *Under review for possible development are:*

  - The Beers list of medications that should not be provided to elderly patients (although it is no longer known as the Beers list)

– Update of Facts About Older Adults and Medicines (revision)

Dr. Schell also noted that the board's staff plans to develop a section of its Web site as a resource on prescription errors. The board has been actively involved in a number of activities aimed at reducing errors, including the board's quality assurance program requirements that mandate that pharmacies evaluate every prescription error.

Public awareness has been heightened by the recently released SCR 49 Report on Medication Errors.

The board's Web site will include data such as that presented at the July 2006 Board Meeting on prescription error data identified by the board through investigations of consumer complaints. It will also include information from other sources – ways to prevent errors, frequently confused drug names, etc. It will have link to other Web sites as well.

Staff plans to have this section of the Web site developed by the October Board Meeting, when the new Web site is rolled out.

Dr. Schell asked if there were any questions or comments regarding the development of new consumer brochures. There were none.

6. Miscellaneous Consumer Issues/Articles in the Media

Dr. Schell stated that several articles of consumer interest were included in this meeting materials packet. During this meeting, the committee can review and discuss these items.

Dr. Schell brought the committee's attention to the Wall Street Journal article dated March 15, 2007 entitled "Many Americans Disregard Doctors' Course of Treatment." He said that an interactive health care poll revealed that 44 percent of Americans say they or an immediate family member have ignored a doctor's course of treatment or sought a second opinion because they felt the doctor's orders were unnecessary or overly aggressive. This was a concern as medicine could be misused. Fifty-five percent of people thought under-treatment was an issue too. This will fold into our discussions about medication safety.

Dr. Schell noted that the San Diego Union-Tribune article dated March 13, 2007 entitled "Health Illiteracy Hampers Wellness" spoke about patients walking out of doctor's offices not knowing what they were told. Patients say they don't have enough time with the doctors. They don't know what meds they're getting or what they're for. These news articles will be important during deliberations about medication safety.

Dr. Schell also noted the American Society of Health-System Pharmacists (ASHP) press release dated March 1, 2007 regarding accidental poisonings. He referred to six tips for caregivers of seniors provided by the ASHP including:

- Keep a list of your medications
- Communicate
- Learn about their medicines
- Use one pharmacy
- Keep a journal
- Maintain a schedule

The press release also provided five tips for caregivers of children.

Dr. Schell asked if there were any comments or questions from the public. There were none.

7. Update on the Board's Public Outreach Activities

Dr. Schell summarized the board's public outreach activities performed since the January 2007 report to the board. There have been six presentations to professional association meetings and a booth staffed at two public outreach fairs.

Dr. Schell stated that future presentations are planned.

Dr. Schell stated that the board places an emphasis on these requests for public and licensee education.

8. Review and Discussion of the SCR 49 Medication Errors Report

Dr. Schell stated that on March 6, 2007, the Medication Errors Panel, brought together by SCR 49, released its report on "Prescription for Improving Patient Safety: Addressing Medication Errors." A copy of the report was included in the meeting material packet, as was the executive summary and an article from The Sacramento Bee.

There are 12 recommendations in the report as follows:

A. Communication Improvements, with an emphasis on improving the quality and accuracy of communications between prescribers, pharmacists and patients.

1. Improve the legibility of handwritten prescriptions and establish a deadline for prescribers and pharmacies to use electronic prescribing.
2. Require that the intended use of the medication be included on all prescriptions and require that the intended use of the medication be included on the medication label unless disapproved by the prescriber or patient.

3. Improve access to and awareness of language translation services by pharmacists at community pharmacies and encourage consumers to seek out pharmacists who speak their language and understand their cultural needs.
4. Promote development and use of medication packaging, dispensing systems, prescription container labels and written supplemental materials that effectively communicate to consumers accurate, easy-to-understand information about the risks and benefits of their medication, and how and where to obtain medication consultation from a pharmacist.

B. Consumer Education to increase consumer awareness regarding the proper use – and dangers of misuse – of prescription and over-the-counter medications.

5. Identify and disseminate information about best practices and effective methods for educating consumers about their role in reducing medication errors.
6. Establish an ongoing public education campaign to prevent medication errors, targeting outpatients and persons in community settings.
7. Develop and implement strategies to increase the involvement of public and private sector entities in educating consumers about improving medication safety and effectiveness.

C. Pharmacy Standards and Incentives, with a focus on information and mediation consultations given by pharmacists to their patients as a means of educating consumers about drug safety.

8. Help ensure quality and consistency of medication consultation provided by pharmacists within and among pharmacies.
9. Establish standards for Medication Therapy Management programs and create incentives for their implementation and ongoing use by pharmacists and other healthcare providers.

D. Training and Education for healthcare providers on various medication safety practices

10. Create training requirements for pharmacists and other healthcare professionals that address medication safety practices and related programs, including medication consultation and medication therapy management programs.

E. Research, with a focus on obtaining information about the incidence, nature and frequency of medication errors in the community setting.

11. Establish and support efforts to collect data regarding the nature and prevalence of medication errors and prevention methods for reducing errors, especially focused on persons at high risk for medication errors and in community, ambulatory and outpatient settings.

F. Other: relating to the obstacles that pharmacists face in providing drug consultation to patients, encompassing a variety of factors such as manpower shortages and lack of payment systems to cover the time and expense associated with these tasks. Before additional duties can be imposed upon pharmacists in outpatient settings, these issues must be addressed:

12. Convene a panel of stakeholders to identify and propose specific actions and strategies to overcome barriers to qualified pharmacists being recognized and paid as health care providers.

Dr. Schell said that this meeting is the first opportunity for the board to review this report, and that the board will closely review and work with the findings of the report. He asked for comments on the report.

Ms. Bauer said it has been fun to be here today. She liked the meeting packet, the material on the website, and all the activities and materials the board is producing. She stated that this committee was established in 1995 as part of the strategic plan. It was started with lots of hope and $10,000, and she was the first committee member.

Ms. Bauer stated that in 1999 the committee received an award from NCPIE. At that time, they were astounded that 50% of medications were taken incorrectly because people are not well educated or not licensed – it's a gap in communication between the pharmacy and the patient.

Ms. Bauer stated that the goal of educating consumers and pharmacists is still relevant. The profession of pharmacy is about talking to the patient. Patient consultation is the most effective way to be sure patients receive the right medication, at the right time, and take it in the right way. She stated that with respect to the Medication Errors Panel, she will provide the board with summaries of all testimony heard by the SCR 49 Panel and that forms the basis of the recommendations made in the report.

Ms. Bauer encouraged the board to find ways to increase communication between pharmacists and patients. In her experience, when consultations take place, errors are caught or do not happen in the first place.

The pharmacy industry spends billions per year – some of these improvements recommended in the SCR 49 report will be very cost effective and prevent patient harm. She applauds the work that the board is doing and looks forward to working with the board in the future. The last person to speak to the consumer should be the pharmacist, and hopefully not a clerk handing the patient a bag. The practice of pharmacy must be part of the future marketplace. English literacy, health literacy, cultural issues, handicaps in vision and hearing all contribute to problems that consumers have in taking medications.

Dr. Schell asked if there were any other comments on the Medication Errors Report.

Fred S. Mayer, RPh, MPH, President of Pharmacists Planning Service, Inc. (PPSI) distributed a document containing 13 simple points on how to fix the system. He endorses the four pieces of legislation addressing prescription errors. Mr. Mayer elaborated on the 13 points, and other materials in his handouts. He spoke briefly and passionately about the importance of pharmacists consulting with patients. He also encouraged dispensing of 90 day supplies of drugs instead of 30 day supplies, because it will allow more time for pharmacists to consult with patients because fewer patients will need to enter a pharmacy each month.

Mr. Mayer asked the committee what they would do with this information. If nothing is done, then we will have more media coverage as was shown on the recent 20/20 TV program. He believes that pharmacists can prevent 50 percent of medication errors with consultations.

Mr. Hough noted that his favorite page is page 35 of Mr. Mayer's hand-out showing the tiny print that consumers are expected to read disclosing warnings about a specific drug.

Mr. Mayer said the simplest solution is patient counseling. He said that he can't spend time counseling his patients when he's filling 200 prescriptions in a day. He believes that between counseling on all prescriptions and giving a 90 day supply at a time, this will help reduce medication errors.

Dr. Schell said he would like to acknowledge everyone for testifying today. The board has already started to move on the medication errors issue. The board is taking this issue very seriously. He invited the public to send letters or documents to the board, and that the board appreciates all the speakers.

Ms. Herold stated that during the April 2007 Board Meeting, we will have time set aside to talk about SCR 49, so it will address the issue as a whole, not as a subcommittee.

Dr. Schell added that the committee will echo comments submitted to the board for those who cannot attend.

9. Update of the Committee's Strategic Plan for 2007-08

In July 2006, the board finalized its strategic plan for 2006-2011. Each year in the spring, the board revises its plan to keep it current. It is now time to review the plan for 2007-08.

Dr. Schell stated that we don't have enough voting members today, so this matter will be taken up at the next board meeting.

10. Creation of New Board Web Page and Addition of Materials to Board's Web Site

In July 2006, the board completed its redesign of the board's Web site to conform to the parameters established by the Governor's Office. This completed a process started about a year before to redesign the board's Web site so it was consistent with other state agencies.

The board recently received notice that it is time to redesign our Web page again to confirm to the new look for state agency web pages. The deadline for conversion to the new format is November 2007.

Board staff has begun work on the new format, and should meet the November deadline. This time the board will be on the leading edge of the conversion, instead of being among the last to convert to the new format.

Ms. Abbe added that two new Web pages had recently been posted to the board's Web site under the section devoted to "Information for Consumers." Each of the two new Web pages provided helpful links for consumers as follows:

FDA Information Regarding Medications and Medical Devices

- FDA Recalls, Market Withdrawals and Safety Alerts in the Last 60 Days
- FDA Information Regarding Medication Errors
- Information About Products Regulated by the FDA
- Drug Interactions: What You Should Know, FDA
- Drugs@FDA, a Database Offering Detailed Information About All Drugs Approved by the FDA
- Be an Active Member of Your Health Care Team, an FDA Presentation
- FDA Safety Information and Adverse Event Reporting Program

Medication Safety and Drug Interaction Checker Web Sites

- American Society of Health-System Pharmacists Offer Tips and Advice for Using Medications Safely and Effectively
- As You Age: A Guide to Aging, Medicines and Alcohol, U.S. Department of Health and Human Services
- Consumer Reports Guides to Prescription, OTC and Natural Medicines, http://www.consumerreports.org/mg/a-z-drug-index/A.htm and http://www.consumerreports.org/mg/natural-medicine/index.htm (Note: Some pages on the Consumer Reports site require a paid subscription)
- My Medicines, a form for listing your medications and supplements
- Herb and Drug Interactions, Mayo Clinic
- Your Medicine: Play It Safe, Agency for Healthcare Research and Quality
- Caremark - click on Drug Interactions under the heading Health Resources

- Drugs.com
- Drugstore.com
- Express Scripts - click on Check Interactions
- Medscape - search for "drug interaction checker"
- University of Maryland Medical Center
- Walgreens (Requires free site registration)
- Wal-Mart - click on Learn About Drug Interactions under heading for Drug Information

Adjournment

There being no additional business, Chairperson Schell adjourned the meeting at 3:45 p.m.

Prescription for Improving Patient Safety: Addressing Medication Errors

A report from
The Medication Errors Panel
Pursuant to California Senate Concurrent Resolution 49 (2005)

March 2007

About the Medication Errors Panel:

Recognizing the significant and growing public health concern of medication errors, Senator Jackie Speier authored Senate Concurrent Resolution (SCR) 49 (2005), sponsored by the California Pharmacists Association. Adopted September 14, 2005, the Resolution called for the creation of an expert panel to study the causes of medication errors in the outpatient setting and to recommend changes to the health care system that would reduce errors associated with prescription and over-the-counter medication use.

The Medication Errors Panel, assembled in 2006, consisted of two Senators, two Assembly members and 13 persons representing academia, consumer advocacy groups, health professions (medicine, nursing, public health and pharmacy), health plans, the pharmaceutical industry, and community pharmacies. Throughout 2006, Panel members gave a tremendous effort to this study and met at the state capitol 12 times to hear and discuss testimony from 32 invited speakers who included many widely respected state and national leaders in the fields of pharmacy practice, medicine, medical technology, healthcare regulation, academia, and the pharmaceutical industry.

The following is the report of the Panel complete with its consensus recommendations.

Acknowledgements

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EXECUTIVE SUMMARY

The Problem of Medication Errors

A medication error is any preventable event occurring in the medication-use process, including prescribing, transcribing, dispensing, using and monitoring, that results in inappropriate medication use or patient harm. These errors and their consequences present a significant public health threat to Californians.

While most consumers and healthcare providers do not often associate poor health outcomes with adverse drug events – frequently the result of medication errors – the human and financial costs of the problem are staggering.

The most recent estimate of costs associated with drug-related morbidity and mortality in the US exceeds $177 billion per year. Amazingly, this amount is significantly greater than the amount actually spent on prescription drugs during the same year. In terms of patient harm, the Institute of Medicine projects that at least 1.5 million Americans are sickened, injured or killed each year by medication errors. Extrapolating these figures to California suggests that on an annual basis, the problem costs our state $17.7 billion dollars and causes harm to 150,000 Californians.

Perhaps the most concerning aspect of these errors is that the tremendous human and financial costs are not the result of some serious disease, but rather, well-intentioned attempts to treat or prevent illness.

In an effort to address this significant and growing problem, in 2005 Senator Jackie Speier authored Senate Concurrent Resolution 49, sponsored by the California Pharmacists Association. This resolution, adopted September 14, 2005, called for the creation of an expert panel to 1) study the causes of medication errors in the community setting, and 2) recommend changes in the health care system that would reduce errors associated with over-the-counter and prescription medications in the outpatient setting.

The Panel, assembled in 2006, consisted of two Senators, two Assembly members and 13 persons representing academia, consumer advocacy groups, health professions (medicine, nursing, public health and pharmacy), health plans, the pharmaceutical industry, and community pharmacies. Throughout 2006, the Panel met at the state capitol 12 times to hear and discuss testimony from 32 leaders in the fields of pharmacy practice, medicine, medical technology, healthcare regulation, academia, and the pharmaceutical industry.

Reducing Errors through a "Systems Approach"

Testimony provided to the Panel indicated that efforts to address errors are best targeted not at a particular group of individual "wrong doers," but rather at faulty systems, processes, and conditions that either lead people to make mistakes or fail to prevent them. Consequently the Panel took a "systems approach" for studying the problem and developing its recommendations.

After spending considerable time examining each part of the medication-use process – prescribing, dispensing, using (administering/self-administering) and monitoring – and the inter-relationships of each component, the Panel identified four key medication-use systems/processes and three key stakeholder groups which served as the focus of its recommendations.

Key Processes and Stakeholders

The four key processes which the Panel believes could be better designed to reduce and prevent medication errors are those related to:

1) **The transcription and transmission of prescriptions** (i.e. the methods prescribers use to document a prescription order and communicate that order to the pharmacy where it will be filled).

2) **The education of the consumer** regarding the purpose of the treatment, the effective use of the medication, and the monitoring of signs and symptoms that may indicate efficacy or toxicity.

3) **Healthcare provider payments and incentives** which can directly or indirectly influence providers to pursue behaviors designed to reduce medication errors.

4) **Healthcare provider training and licensure** which could foster a better understanding among providers about the seriousness of medication errors and the behaviors to adopt that will reduce them.

The three key stakeholder groups which the Panel believes will be critical in affecting the necessary changes to these processes are:

1) **Consumers and consumer oriented organizations** such as the California Department of Consumer Affairs; advocacy organizations (e.g. AARP, American Heart Association); community-based organizations; and private and public foundations.

2) **Healthcare providers and related organizations** such as academic institutions, professional societies and advocacy groups, and licensing/oversight Boards.

3) **Healthcare purchasers, payers, regulators and related organizations** such as the State of California, its Department of Health Services and the Medi-Cal program; private purchasers of health care such as employers; commercial insurance companies which administer health benefits for both public and private sector purchasers; the

California Departments of Insurance and Managed Health Care which regulate these insurance companies; pharmacy benefit managers which focus specifically on the administration of pharmacy benefits; and of course, the Legislature and Administration of the State of California which possess the potential to influence and/or establish accountability for these groups.

Based on the analysis of these four key processes and three key stakeholder groups, the Panel developed 11 consensus recommendations within five subject areas, and a twelfth recommendation to further consider and address issues that went beyond the scope of the Panel's purpose.

Recommendations

A. **Communication Improvements,** with an emphasis on improving the quality and accuracy of communications between prescribers, pharmacists and patients. Specific recommendations are:

1) Improve legibility of handwritten prescriptions, and establish a deadline for prescribers and pharmacies to use electronic prescribing.

2) Require that the intended use of the medication be included on all prescriptions and require that the intended use of the medication be included on the medication label unless disapproved by the prescriber or patient.

3) Improve access to and awareness of language translation services by pharmacists at community pharmacies and encourage consumers to seek out pharmacists who speak their language and understand their cultural needs.

4) *Promote development and use of medication packaging, dispensing systems, prescription container labels and written supplemental materials that effectively communicate to consumers accurate, easy-to-understand information about the risks and benefits of their medication, and how and where to obtain medication consultation from a pharmacist.*

B. **Consumer Education** to increase consumer awareness regarding the proper use – and dangers of misuse – of prescription and over-the-counter medications. Specific recommendations are:

5) Identify and disseminate information about best practices and effective methods for educating consumers about their role in reducing medication errors.

6) Establish an on-going public education campaign to prevent medication errors, targeting outpatients and persons in community settings.

7) Develop and implement strategies to increase the involvement of public and private sector entities in educating consumers about improving medication safety and effectiveness.

C. **Pharmacy Standards and Incentives,** with a focus on information and medication consultations given by pharmacists to their patients as a means of educating consumers about drug safety. Specific recommendations are:

8) Help ensure quality and consistency of medication consultation provided by pharmacists within and among pharmacies.

9) Establish standards for Medication Therapy Management (MTM) programs and create incentives for their implementation and ongoing use by pharmacists and other healthcare providers.

D. **Training and Education for Healthcare Providers** on various medication safety practices. The specific recommendation is:

10) Create training requirements for pharmacists and other healthcare professionals that address medication safety practices and related programs, including medication consultation and medication therapy management programs.

E. **Research,** with a focus on obtaining information about the incidence, nature, and frequency of medication errors in the community setting. The specific recommendation is:

11) Establish and support efforts to collect data regarding the nature and prevalence of medication errors and prevention methods for reducing errors, especially focused on persons at high risk for medication errors and on community, ambulatory and outpatient settings.

In addition to these five subject areas, the Panel identified a sixth that needs to be addressed but which it determined was beyond its scope. This issue relates to the many obstacles that pharmacists face in providing drug consultation to their patients which encompasses a variety of factors such as manpower shortages and the lack of payment systems to cover the time and expense associated with these tasks. Before additional duties can be imposed on pharmacists practicing in outpatient settings, the Panel recognizes that these issues must be addressed. Therefore the Panel put forth a twelfth recommendation:

12) Convene a panel of stakeholders to identify and propose specific actions and strategies to overcome barriers to qualified pharmacists being recognized and paid as healthcare providers.

SECTION I: REPORT OF THE PANEL

Background & Overview

The Problem of Medication Errors

For the purpose of its work, the SCR 49 Panel defined a medication error as "any preventable event occurring in the medication-use process, including prescribing[1], transcribing, dispensing, using and monitoring, which results in inappropriate medication use or patient harm."

Errors involving prescription and over-the-counter medications represent an enormous public health problem. When an error occurs, the best possible outcome is for a medication to simply not elicit an adverse result. Even under this best-case scenario, medication errors have a significant negative impact on the US healthcare system, contributing to increasing costs for consumers, employers and other persons who pay for health care. Even worse than the financial cost is the harm to consumers' health and well-being caused by medication errors, which can range from mild to life-threatening and even death.

The scope and severity of medication errors and the related consequences have been documented by many health researchers. For the year 2000, experts estimated the overall cost of drug-related morbidity and mortality to be in excess of $177.4 billion.[2] That amount greatly exceeds the $120.8 billion spent on prescription drugs during that year.[3] In terms of patient harm from medication errors, the Institute of Medicine (IOM) estimates that at least 1.5 million Americans are sickened, injured or killed each year by medication errors.[4] Extrapolating these figures to California suggests that on an annual basis, the problem costs our state $17.7 billion dollars and causes harm to 150,000 Californians.

Perhaps the most disturbing aspect of medication errors is that these tremendous human and financial costs are not the result of some serious disease, but rather well-intentioned efforts to treat or prevent illness.

The Importance of Addressing Errors in Community Settings

When imagining places where medication is dispensed and taken or "administered," many people think of hospitals or other health care facilities. But, in fact, the vast majority of medications are taken by out-patients in "community settings," including homes, schools, offices, independent living facilities, and children or adult day care centers. Last year, over 5,000 licensed "community" pharmacies in California filled about 400 million prescriptions for community dwelling individuals.

In community settings a person often has a prescription written by his or her health care provider, usually a doctor, and has it filled at a community pharmacy, often a neighborhood drug-store, supermarket or other retail outlet. After a consumer receives medication from a community pharmacy, they or their caregiver is largely left on their own to take/administer the medication and monitor for signs and symptoms of efficacy or toxicity.

Compounding the problem of medication errors in community settings are the increasing numbers of consumers that buy and use over-the-counter medicines, herbals or other alternative treatments. While many consumers believe the "all-natural" or non-prescription status of these therapies suggests inherent safety, these products do have the potential to cause adverse effects and interact with prescription medications or each other.

In spite of incredible potential for medication errors to occur in the community setting, much of the attention paid to the problem thus far has focused on hospital and other institutional settings. In fact, there are already many state and national efforts underway aimed at reducing errors in these settings. This, coupled with evidence regarding the magnitude of the problem outside of institutional settings, led the Panel to focus on making recommendations about medication errors that occur in the community.

[1] While the Panel identified drug and dose selection as a process (i.e. prescribing) where errors can occur, its analysis and recommendations were focused on the areas of the medication-use process that occur *after* the point where prescribers consciously make such decisions.

[2] Ernst FR, Grizzle AJ. Drug-related morbidity and mortality: updating the cost-of-illness model. J Am Pharm Assoc 2001;41:192-9.

[3] US Office of the Actuary National Health Expenditure Data. 2000

[4] Institute of Medicine (IOM). (2007). *Preventing medication errors: Quality chasm series.* P. Aspden, J. Wolcott, J. L. Bootman, & L. R. Cronenwett (Eds.). Washington, DC: The National Academies Press.

U.S. and California Medication Error Data

There is no organization responsible for maintaining comprehensive data about medication errors in the United States or California. Several national organizations collect information related to medication errors, but their data is not comprehensive and has many limitations – it may focus on health care professionals, not consumers or on health care facilities, not community settings – or organizations may mix data about medication errors with other data – for example, data about "medical" errors or "adverse drug events." Also, organizations often define "medication error" differently, creating challenges with combining or comparing data.

Finding medication error data specific to California is even more challenging. One could extrapolate from data at the State's Board of Pharmacy and Medical Board, although neither body is charged with actively monitoring medication errors or collecting comprehensive error data. They simply document and respond, as appropriate, to complaints made by health care professionals or consumers about medication errors and other issues related to their areas of oversight.

California-specific research studies identified by the Panel did not include information about community-settings, only hospitals and residential care settings. National organizations, including the federal Food and Drug Administration (FDA) and the nonprofit Institute for Safe Medication Practices (ISMP), contacted by the Medication Errors Panel staff were unable to report medication error data specific to California.

Types of Medication Errors

In the community setting, there are three general types of medication errors that can occur: those related to the prescribing process; those that occur when the medication is dispensed at the pharmacy; and those related to the consumer's use of the medication.

Prescribing Errors

The first step in obtaining a prescription medication occurs when a consumer visits a physician, or other health care professional with prescribing authority, and receives a prescription.

In order to avoid selecting a drug that could be inappropriate or harmful to a patient, it is important for the prescriber to have access to the patient's complete health information record at the time the patient is being seen. The patient information should include all medicines the patient is taking, lab test results, other physicians the patient has seen, and any past hospitalizations or drug allergies.

The Panel heard testimony that prescribers in California often do not have ready access to vital patient information at the time that a prescription is written. This is largely due to continued reliance on paper-based documentation systems which lend themselves to having important patient information be missing, inaccessible, illegible and inaccurate – all of which can contribute to prescribing errors.

While the Panel identified drug and dose selection as a place where errors can occur, it decided to focus its analysis and recommendations on areas of the medication-use system that occur *after* the point where such decisions are made. From a prescribing standpoint, this includes practices related to the transcription and transmission of prescription information which may contribute to patients not receiving the intended medication or dose. More information on these types of errors is included in the next section of this report.

Dispensing Errors

Dispensing errors occur when a patient is given a medication other than the one intended by the prescriber. These types of errors are often the result of sound/alike or look/alike drugs, according to testimony provided by Patricia Harris, Executive Officer of the California Board of Pharmacy. Ms. Harris noted that an increasingly reported mistake is the dispensing of the "right drug" to the "wrong person," often the result of similar names shared by several members of a family, many of whom may speak limited English.

To help address errors such as these, the California Board of Pharmacy created a requirement in 2002 for every pharmacy to adopt a quality assurance program. Such programs require pharmacies to document and identify the cause of any errors that occur, and develop systems and workflow processes designed to prevent the same type of error from occurring in the future.

The Panel heard testimony regarding other types of dispensing errors from Michael Cohen, RPh, ScD, founder and director of the Institute for Safe Medication Practices (ISMP). His data is based on voluntary reports of errors received by the ISMP from health practitioners and consumers nationally over many years. A summary of all the major medication error causes identified by

ISMP is listed in Table 1. Causes of dispensing errors include confusing drug names, labels, and/or packaging (look/sound alike problems); environmental, staffing, or workflow issues (poor lighting, excessive noise, workload, interruptions); lack of quality control or independent verification systems; missing patient information (allergies, age, weight, pregnancy); and missing drug information (outdated references, inadequate computer screening).

In relation to the last two causes, it is pertinent to note a California regulation which requires pharmacies to maintain records on all patients who have prescriptions filled at their pharmacy for at least one year. These records must include "patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent".[5] For the purposes of creating as complete a record as possible in one location, the Board of Pharmacy recommends that consumers use only one pharmacy when feasible.

By reviewing patient records, a dispensing pharmacist can determine whether a new medication the patient is being prescribed is appropriate and compatible (not contraindicated or in conflict with) with other medications the patient is already taking. Reviewing patient records in this way is called Drug Utilization Review (DUR) and is a very important safety feature.

Administration/Medication Use Errors

A key characteristic of the community setting that contributes to medication errors is that medications are administered by patients or other persons who are not health care professionals trained to do so. This is in sharp contrast to inpatient hospital settings where prescribers write orders for medications on patients' medical charts and drugs are subsequently administered by health care professionals. In hospitals, patients are often passive, and rely on others for their treatment. In community settings the opposite is true, and medication use is almost completely dependent upon consumer knowledge and motivation which can often be lacking. In fact, it has been estimated that people who are prescribed self-administered medications typically take less than half the prescribed doses.[6]

Many consumers simply do not understand what medications they are taking, their importance, their contraindications, or proper usage. In addition, consumers may not be asked by their health care professionals what non-prescription medications or supplements they are taking and may not know the importance of volunteering this information to avoid problems such as therapeutic duplications or interactions.

Because the majority of medication errors in community settings are made by consumers, it is clear that real progress will require significant efforts to improve consumers' knowledge, skills and motivation to use their medications correctly. Health care professionals and others involved with prescribing, dispensing, administering and monitoring medication use in community settings can all help achieve these goals.

TABLE 1: Institute of Safe Medication Practices' Major Causes of Medication Errors

- **Critical patient information is missing** (allergies, age, weight, pregnancy, etc.)
- **Critical drug information is missing** (outdated references, inadequate computer screening, etc.)
- **Miscommunication of drug order** (illegible, incomplete, misheard, etc.)
- **Drug name, label, packaging problem** (look/sound alike, faulty drug identification)
- **Drug storage or delivery problem**
- **Drug delivery device problem** (poor device design, IV administration of oral syringe contents, etc.)
- **Environmental, staffing, workflow** (lighting, noise, workload, interruptions, etc.)
- **Lack of staff education**
- **Patient education problem** (Lack on patient consultation, non-compliance)
- **Lack of quality control or independent check systems in pharmacy**
- **Physician knowledge is lacking** (when a drug comes to market that replaces an existing one or several ones, i.e., a combination drug may mean that a person takes it once a week instead of daily)

[5] California Code of Regulations, Title 16, Section 1707.1

[6] Haynes RB, Yao X, Degani A, Kripalani S, Garg AX, McDonald HP. Interventions for enhancing medication adherence. Cochrane Database Syst Rev 2005;(4):CD000011.

Working Towards Patient Safety: A Systems Approach

Several experts who testified to the Panel cited multiple reports indicating that efforts to address errors are best targeted not at a particular group of individual "wrong doers," but rather at faulty systems, processes, and conditions that either lead people to make mistakes or fail to prevent them. The Panel consequently agreed to take a "systems approach" for studying the problem and developing its recommendations.

As a result, the Panel spent considerable time examining each part of the medication-use process – prescribing, dispensing, using (administering/self-administering) and monitoring – and the inter-relationships of each component. The Panel determined the medication-use system to be quite complex involving a multitude of stakeholders. A detailed explanation of the entire system is beyond the scope of this report, but through its work, the Panel identified four key processes and three key stakeholder groups which served as the focus of its recommendations.

Key Medication Use Processes

Prescription, Transcription and Transmission Processes

Once a prescriber decides what medication and dose to prescribe, he or she must find a way to communicate that information to the pharmacy where the patient will have their prescription filled. It is through this communication where a significant proportion of prescription errors occur.

Often, prescribing information is communicated via handwritten prescriptions which employ the use of Latin abbreviations that can sometimes be confusing. These prescriptions can be illegibly written and may be submitted to pharmacies via fax which can further contribute to legibility problems. The most frequent problems of this sort are related to medication names (particularly for drugs that have "look-alike" names such as those in Table 2), and medication strengths.

Table 2: Look-alike/Sound-alike Drug Name Examples	
Seroquel 200mg	Serzone 200 mg
Aciphex	Aricept
Hydroxyzine	Hydralazine
Zyprexa 10mg	Zyrtec 10mg
Quinine 324mg	Quinidine 324mg

Alternatively, the prescription can be communicated to a pharmacy verbally over the telephone but this mode of communication is not without its own challenges, such as the confusion of "sound alike" drugs (see examples in Table 2). These problems can be exacerbated through the use of non-professional medical office staff who may not be familiar with drug names and medical terminology. It should also be noted that whenever a person other than the prescriber is used to communicate prescription information over the telephone, they are almost always reading information that was written by another individual, which of course is subject to the same legibility issues as hard-copy prescriptions.

Electronic or "e-prescribing" is, most broadly, the transmission of prescription information from a prescriber to a pharmacy using computer technology. While recent efforts have been made by some prescribers and pharmacies to adopt e-prescribing, medical offices has been slow to do so, predominantly because of high-costs and a lack of incentives for providers to change their practices. Compounding the situation is the fact that state and federal e-prescribing standards have not been set or are inconsistent or conflicting.

Even when medical offices have the technology to facilitate e-prescribing, most do not fully employ it. Rather, they simply use their electronic record systems to send computer generated prescriptions via fax.

While some persons may consider the transmission of a prescription from a computer to a fax machine as "e-prescribing," others believe that transmitting a static image, picture or facsimile is of limited value to helping ensure information accuracy, quality control or data analysis. The benefit is maximized from e-prescribing only when prescriptions are transmitted in a manner so that a recipient may use and analyze the information without having to manually copy or enter the data received.

The end goal with e-prescribing should be full system connectivity between pharmacies and medical offices to allow for *two-way* communication. Such connectivity could better leverage pharmacy data and has the potential to notify prescribers of possible medication-related problems before they occur.

Another problematic aspect of the prescribing process is that it frequently does not engage the consumer to an appropriate degree. All too often patients leave the prescriber's office without having the adequate medication-related information effectively communicated to them. Of particular concern are the consumers who present to the pharmacy without knowing the most basic information such as the name of the medication or what it is for. Without this minimal knowledge, there is very little consumers can do on their own to identify errors – even the most obvious ones such as receiving the wrong medication.

Consumer Education Processes

At the center of the medication-use process is the consumer. In the community setting, successful medication use is heavily dependent upon consumer knowledge and motivation which can often be lacking. When a person is not well-informed and motivated to manage their therapy, they cannot be expected to take their medication correctly or be an active partner in screening for signs and symptoms of medication efficacy or toxicity. There are a variety of complex reasons why many consumers allow themselves to be passive participants in the medication use process but the most significant is that consumers are largely unaware of, or do not accept the personal risks associated with medication use.

In addition to the consumer education challenges that pertain to the prescribing process, the Panel identified other aspects of the medication use process that could be modified to provide patients with better information and tools to reduce medication errors.

Pharmacist Consultation

While pharmacists are widely known for their dispensing activities, they can also play an important role educating consumers to ensure that the patient or their caregiver knows what the medicine is for, how to take it correctly, and what signs/symptoms should be monitored to assess for efficacy and toxicity.

State regulation requires pharmacists to provide a verbal medication consultation to the patient or the patient's agent each time a new medication is dispensed, or whenever an existing medication therapy is dispensed with a change in dosage form, strength or instructions for use.[7] This consultation is to include "directions for use and storage and the importance of compliance with the directions." Also included should be a "discussion of the precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered."

In spite of these requirements, the Panel received testimony suggesting considerable variability in the quality of these consultations as well as the consistency to which they are offered by pharmacy staff and utilized by consumers. The reasons for this are not well defined but there appear to be contributing factors from both the pharmacist end (lack of time and incentives) and the consumer end (lack of awareness regarding availability and perceived value).

While there is not a lot of data about the effectiveness of this dispensing-related counseling, it is reasonable to assume that the significant number of consumer-related medication errors could be positively influenced by greater efforts in this arena, particularly with at risk populations including seniors and minority patients.

Prescription Labels and Labeling

The information that consumers need to know about their medication is often complex and may include unfamiliar language or concepts. Expecting a consumer to retain all the pertinent knowledge from a brief verbal encounter may not be reasonable in many instances. For this reason, it is important that consumers also receive written information regarding their prescription.

Often-times however, even this information can be forgotten and lost, and in those instances, the consumer may be left with nothing more than the prescription packaging and label to guide them. Testimony provided to the Panel identified many limitations related to the prescription label as an effective communication tool. These included the limited size of a prescription label (approximately 2 x 3 inches) which, due to established pharmacy systems, processes, and drug container variability would be functionally and financially difficult for the pharmacy industry to change.

Further complicating matters is the fact that there is already a significant amount of information required by California law to be printed on the label.[8] The most recent label requirement went into effect on January 1, 2006 and was created to help consumers identify erroneously filled prescriptions by mandating that pharmacies include the physical description of the dispensed medication, including its color, shape, and

[7] California Code of Regulations, Title 16, Section 1707.2

[8] California Business and Professions Code 4076

any identification code that appears on the tablets or capsules.

While this requirement is obviously directed at reducing errors, one might question the utility of some of the other label requirements which include the date of issue, the name of the pharmacy, the address of the pharmacy, the prescription number or other means of identifying the prescription, the name of the patient, the name of the prescriber, the name of the medication, the name of the medication's manufacturer, the strength of the drug, the quantity dispensed, the expiration date of the drug, and of course the directions for use. Given the limited space available, are all of these elements the most valuable pieces of information for the patient?

Regarding the directions of use, even when individuals are able to read and repeat back the directions, they may still not understand how to take the medication. This is particularly a problem for individuals with limited health literacy (the ability to read, understand and act on health information). A recent study by Davis, Wolf and others showed that even though 70.7% of patients with low literacy could correctly read and repeat the instructions, "Take two tablets by mouth twice daily," only 34.7% could accurately demonstrate the actual number of pills to be taken daily.[9] In this study the researchers found that it was common for consumers to make mistakes when dosing medicine for themselves, their elderly parents, and their children.

Tailoring and Targeting Consumer Education Efforts

To maximize the impact of consumer education activities, efforts will need to be tailored and targeted to individuals who are likely to achieve the greatest benefit. While the Panel did not come to consensus on the most important subset of consumers that are at "high risk" for medication errors, it did acknowledge that there are a variety of factors which may increase an individual's risk for experiencing a medication error.

In addition to 1) low health literacy, these can include; 2) limited English proficiency; 3) cultural incongruence with healthcare providers; 4) physical, cognitive and/or other impairments that make understanding and/or complying with medication instructions difficult; 5) age at either end of the age spectrum (the variability of a medication's response, metabolism and dose increases in children and seniors); 6) multiple medications; 7) multiple prescribers; 8) non-prescription medication use (including herbals, dietary supplements alcohol and tobacco); and 9) medication procurement from more than one pharmacy including mail-order. These factors must be taken into consideration in the development of any consumer education efforts.

Provider Payment/Incentive Processes

Incentives that directly or indirectly influence the behavior of prescribers and pharmacists are a key aspect of the medication use system. Testimony provided to the Panel indicated that prescriber incentives are frequently not aligned to promote spending time educating patients about medication use, or to closely follow patient compliance and medication monitoring parameters.

A fairly recent collaboration between healthcare purchasers, payers and medical groups provides incentives byway of "pay-for-performance" and shows promise for realigning prescriber incentives to reward behavior that results in positive outcomes. However, it is clear that there is still room for improvement in this area, particularly as it relates to safe and effective medication use.

Similarly, pharmacy incentives appear to do little to encourage pharmacist activity in areas related to patient education and the promotion of safe and effective medication use. Since pharmacies generally only receive compensation when a product is dispensed, financial pressures may, in fact, be driving pharmacy processes and personnel to minimize any activities not directly related to product distribution. Ironically, the structure of this financial model may possibly create disincentives for pharmacists to identify and prevent prescriptions with prescribing errors from leaving the pharmacy.

Fortunately, testimony provided to the Panel suggests that the healthcare system may be in the very early stages of what could be a paradigm shift. It appears that increasing numbers of healthcare purchasers and payers are beginning to understand that there is more to consider when it comes to medication than the simple cost of distribution, and the speed and convenience by which it can be put into the hands of consumers. There is a growing recognition that no matter how cheaply a drug can be purchased, the cost is too great if it does not elicit the desired effect, or worse, causes patient harm.

In response to this growing recognition, more and more healthcare purchasers and payers are developing

[9] Davis TC, Wolf MS, Bass PF 3rd, Thompson JA, Tilson HH, Neuberger M, et al. Literacy and misunderstanding prescription drug labels. Ann Intern Med. 2006;146:887-94.

specialized initiatives focused around improving medication use, particularly in target populations where safe, appropriate and effective medication use is critical. These "medication therapy management programs" have been developed for people with particular conditions such as diabetes[10], individuals who have multiple chronic conditions and/or take multiple medications, and those whose medication costs exceed a certain threshold.

Perhaps the most prominent example of this early trend is the requirement placed in the Medicare Modernization Act for sponsors of the Medicare Part D drug benefit to have in place a medication therapy management program designed to promote optimal therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions.

While medication therapy management programs may hold significant promise for reducing medication errors, many issues will need to be resolved before the full potential of such programs can be known and realized. As with any new healthcare initiative, there is uncertainty regarding how the quality and financial returns-on-investment can be maximized by adjusting program variables such as:

- The types of services that are provided (e.g. patient education, medication compliance packaging and comprehensive medication reviews);
- The patient populations that are targeted (e.g. those with a particular condition, medication, cost, or combination thereof);
- The types of providers who deliver various services (e.g. physicians, nurses and pharmacists);
- Service delivery models (e.g. face-to-face, telephone or mail); and
- Payment and documentation methodologies.

Until there is more information and standardization around issues such as these, the spread of medication therapy management programs will likely be slower than perhaps it should. Nonetheless, the fact that innovative purchasers and payers of healthcare are developing novel models to incentivize physicians, nurses, and/or pharmacists to pursue behaviors that will decrease medication errors is a positive step in the right direction.

Healthcare Provider Training and Licensure Processes

Obviously, simply aligning incentives to encourage safe medication practices among healthcare providers is not enough. Providers must also be cognizant of the seriousness of medication errors, know the behaviors to adopt that will reduce errors, and possess the knowledge and skills to effectively execute those behaviors.

Healthcare providers undergo extensive training to become licensed practitioners. Subsequent to licensure, providers must continue training to maintain their licenses. The vast majority of this training is clinical in nature. Most providers receive little education on subjects such as healthcare administration, error prevention, patient communication, and effective, systematic approaches to medication therapy management.

While testimony provided to the Panel indicates that some formal education on topics related to medication errors may be included in provider training programs, the very size of the medication errors problem suggests that the current amount may not be enough. More education in these areas would likely promote greater awareness among providers about what they can do to protect consumers. Informed providers can also be powerful advocates of change in a variety of healthcare settings.

Key Stakeholder Groups

In addition to the four key processes, the Panel identified three key stakeholder groups believed to play critical roles in the development and implementation of initiatives designed to address medication errors.

Consumer-Oriented Organizations

Since the consumer is at the center of the medication use process, it is imperative that all relevant consumer organizations be solicited to join the effort to prevent medication errors. These organizations can play critical roles in educating consumers about medication errors and advocating for healthcare policy and practice changes that have the potential to reduce errors. These groups may be government-related (e.g. the California Department of Consumer Affairs), private foundations, member-benefit organizations (e.g. AARP), or public-benefit organizations.

[10] Information was presented to the Panel on APhA Foundation's Asheville Project. Details can be found at www.aphafoundation.org/programs/Asheville_Project

Healthcare Provider Groups and Related Entities

Healthcare providers such as physicians, nurses and pharmacists are on the front lines of healthcare. In many respects, the burden of reducing medication errors will fall largely on their shoulders. A problem of this scope and size, however, cannot be solved by any single group of individuals, or even by a single sector of the healthcare system acting alone.

Any appreciable reduction in medication errors will require that the entities which support, direct, or influence provider behavior also be actively engaged in addressing this problem. These entities include the academic institutions and professional societies that train providers; the associations that advocate for them; the individuals that mange them; the companies that employ them; and the oversight boards that license and regulate them.

Healthcare Purchasers, Payers and Related Entities

The group that has perhaps greatest opportunity to influence the healthcare system consists of the entities that actually purchase and administer healthcare benefits – and to some extent, those which regulate and oversee the activities of these groups. Many of these entities have the power to decide which healthcare-related behaviors and outcomes are truly of value, and they can create payment structures, non-financial incentives and/or requirements to drive processes and behaviors that seek to deliver those results.

Stakeholders in this group include: the State of California which uses taxpayer monies to purchase, and through its Department of Health Services, administer healthcare benefits through programs such as Medi-Cal; private purchasers of health care such as employers which purchase healthcare for a majority of Californians under 65; commercial insurance companies which administer health benefits for both public and private sector purchasers; the California Departments of Insurance and Managed Health Care which regulate these insurance companies; pharmacy benefit managers which focus specifically on the administration of pharmacy benefits; and, of course, the Legislature and Administration of the State of California which possess the potential to influence and/or establish accountability for these groups.

Conclusion

Based upon the information provided to the Panel, and the identification of these key processes and stakeholders, the Panel developed 12 consensus recommendations in the following subject areas:

- **Communication Improvements** with an emphasis on improving the quality and accuracy of communications between prescribers, pharmacists and patients;
- **Consumer Education** to increase consumer awareness regarding the proper use, and dangers of misuse, of prescription and over-the-counter medications;
- **Provider Standards and Incentives** with a focus on information and medication consultations given by pharmacists to their patients as a means of educating consumers about drug safety;
- **Training and Education for Healthcare Providers** on various medication safety practices;
- **Research** with a focus on obtaining information about the incidence, nature and frequency of medication errors in the community setting.
- **Other Topics to be Addressed** which were determined to be beyond the scope of the Panel but which the Panel recognizes must be addressed hand-in-hand with other practice enhancement efforts in order to assure success in the current and future marketplace and workforce environments.

The recommendations are provided in their entirety in the next section of the report.

SECTION II: RECOMMENDATIONS

A. Communication Improvements

Background:

Improving the quality of communication among prescribers, pharmacists and patients is critical to the success of any effort aimed at decreasing medication errors. The existing process for communication among health professionals and their patients leaves much room for improvement, according to testimony received by the Panel. Indeed, California health practitioners have been slow in their adoption of computer-based patient records and electronic prescribing.

Currently, pharmacist-patient consultation is often compromised by the pharmacist's lack of knowledge of the prescriber's treatment objectives, including such basic information as the condition being treated. Confirming prescriber intent with the patient at the time of dispensing is an additional means of confirming that the medication treatment is understood and properly implemented.

In addition, prescribers' lack of writing legibility has long compromised pharmacists in their efforts to correctly dispense the desired drug product and provide accurate instructions for use. Addressing these two problems of communication between prescribers and pharmacists has been shown to substantially decrease medication errors.

In regard to communication between consumers and their health care providers, an important step would be to adopt techniques that bridge the language and cultural diversity of the patient population in California. This would provide the prescriber and pharmacist with the means to confirm that the medication treatment is understood and will be properly implemented.

Another important improvement in communication between health care providers and their patients would result from improved readability of drug labels and user-friendly packaging.

Goal 1: Improve prescriber-pharmacist communication quality and accuracy regarding prescriptions.

Recommendation 1

Improve legibility of handwritten prescriptions, and establish a deadline for prescribers and pharmacies (allowing for some exceptions) to use electronic prescribing.

Methods

1.1 Require each prescription to be legibly hand written or printed, computer generated or typed, and by 2010 that all prescriptions be computer generated or typed.

The California Board of Pharmacy and the California Medical Board shall review and seek modification of statutory and regulatory requirements as needed to implement adoption of computerized prescriber order entry (CPOE) systems and secure 2-way electronic communication between prescribers and pharmacies, with consideration for identified exceptions to the requirement.

1.2 Require the California Medical Board to collect and disseminate information in order to educate and assist physicians about the benefits of and ways to adopt electronic prescribing systems and supporting CPOE and secure 2-way transmission to pharmacies. Coordinate these efforts with related activities undertaken by the State. For example, Executive Order S-12-06 was issued by Governor Schwarzenegger on July 24, 2006 regarding efforts planned to make reforms regarding healthcare, especially regarding health information technology.

1.3 Require the California Medical Board to adopt regulations by January 1, 2008 that require

prescribers using electronic prescription systems to provide patients with a written "receipt" of the information that has been transmitted electronically to a pharmacy. The document should include at least the patient's name, the dosage and drug prescribed and the name of the pharmacy where the electronic prescription was sent, and should indicate that the receipt cannot be used as a duplicate order for the same prescription.

Goal 2: Improve prescriber-pharmacist and pharmacist-consumer communications to enhance understanding of the intended use of prescribed medication.

Recommendation 2

Require that the intended use of the medication be included on all prescriptions and require that the intended use of medication be included on medication label/labeling unless disapproved by the prescriber or the patient.

Methods

2.1. Require the California Board of Pharmacy and the California Medical Board to pursue necessary statutory and/or regulatory changes to require that by January 1, 2008 these entities coordinate efforts to develop plans to require prescribers to include the diagnosis, medical condition, symptoms or other indicators of the intended use of the medication on each prescription written, allowing for some exemptions.

2.2. Require the California Board of Pharmacy to pursue necessary statutory and/or regulation changes to require that the intended use of any prescribed medication be included on the medication label, unless the prescriber or consumer disapproves, and consumer disapproval is documented by the pharmacist.

Recommendation 3

Improve access to and awareness of language translation services by pharmacists at community pharmacies and encourage consumers to seek out pharmacists who speak their language and understand their cultural needs.

Methods

3.1 The California Board of Pharmacy, Department of Health Services and/or the Department of Consumer Affairs should develop and implement methods, when possible in coordination with other state entities, that are designed to reduce barriers for pharmacists at community pharmacies to access and utilize language translation services. These entities should report their respective related activities planned and undertaken annually on their respective websites and to the Assembly and Senate health committees, beginning January 1, 2008. They should, but not be limited to distributing information to pharmacies about the pharmacies' obligations to provide language translation services and resources for pharmacies to do so via the telephone.

Messages related to this method and goal should be included in the public awareness campaign (Recommendation #6) to inform consumers about their right to use language translation services and availability of these services at community pharmacies and other health care providers.

Recommendation 4

Promote development and use of medication packaging, dispensing systems, prescription container labels and written supplemental materials that effectively communicate to consumers accurate, easy-to-understand information about the risks and benefits of their medication, and how and where to obtain a medication consultation from a pharmacist.

Methods

4.1 Require the California Board of Pharmacy to examine the existing requirements for prescription container labels, prescription containers, and supplementary consumer information, and to consider revising these requirements to encompass required, supplemental consumer information and California Board of Pharmacy contact information.

Require these finding be issued by January 1, 2009 and distributed to the Senate and Assembly Health committees, posted on the California Board of Pharmacy's website and that public notice be made by issuance of a press release.

4.2 Encourage prescription drug plans, health care service plans, and health insurance companies to develop strategies to provide incentives for pharmacies and drug manufacturers to package medications in a manner that increases medication compliance, safety and efficacy.

4.3 Require the California Board of Pharmacy to adopt regulations mandating all pharmacies, including non-resident pharmacies, provide written materials with all dispensed prescriptions that inform consumers of their right to receive a medication consultation from a pharmacist with any new or changed prescriptions. These regulations should include enforcement provisions and the California Board of Pharmacy should make enforcement a priority.

B. Consumer Education

Background:

There is a great need to increase consumer awareness of the proper use, and dangers of misuse, of prescription and over-the counter-medications. Consumers often do not appreciate the potency and risks involved in the use of drugs that are widely advertised and promoted on television, radio and print media.

The California Board of Pharmacy is in an excellent position to spearhead an educational effort directed toward the public concerning drug safety issues. In recent years, the Board has been recognized nationally for its consumer protection efforts. A Board program that capitalizes on their proven expertise in consumer safety and which takes into account health literacy and culturally appropriate communication could be very effective in alerting consumers to potential medication errors, and in motivating them to adhere to their drug treatment instructions. A commitment by the State of California to capitalize on this proven expertise will go far to aid consumers in understanding their role in recognizing potential medication errors and preventing injury from those that do occur.

Goal 3: Improve consumer awareness and knowledge about the risks of medication errors and about steps they can take to reduce their risk of medication errors.

Recommendation 5

Identify and disseminate information about best practices and effective methods for educating consumers about their role in reducing medication errors.

Methods

5.1 Propose legislation allocating funds to and requiring the California Board of Pharmacy to:

a) Identify effective methods for educating consumers about ways to prevent and report medication errors. Include methods that are culturally and linguistically appropriate, especially addressing the needs of persons at high-risk for medication errors.

b) Develop guidelines and/or related regulations to define ways for effectively educating consumers to prevent medication errors. Include both verbal and written education strategies.

c) Disseminate information about the methods and guidelines/standards to specific relevant public and private sector entities, including mail-order (non-residential pharmacies) and pharmacies that dispense prescriptions to outpatients.

d) Improve public access to California Board of Pharmacy services (e.g., telephone, mail, and internet).

Recommendation 6

Establish an on-going public education campaign to prevent medication errors, targeting outpatients and persons in community settings.

Methods

6.1 Pass legislation allocating funds to and requiring the Department of Consumer Affairs and/or the California Board of Pharmacy to oversee development and implementation of a public education campaign to reduce medication errors. Public and/or private funds may be pursued.

The campaign shall be based on principles of public health practice and shall use methods that have been shown effective in educating consumers. The methods shall be culturally and linguistically appropriate and shall be developed in collaboration with other state entities.

The campaign shall develop messages that educate consumers about their medication use, risks, rights and responsibilities and shall include a consumer's right to basic consultation from a pharmacist with each new or changed prescription.

6.2 Require the California Board of Pharmacy and/or the Department of Consumer Affairs to collaborate with appropriate state entities and stakeholder groups, including but not limited to health plans, retail pharmacists, and consumer advocates representing persons at high risk for medication errors to:

a) Develop an evidence-based "safe medication use curriculum" that is designed to be used for educating consumers, and promote its availability to intermediaries, such as health care service plans, colleges, high schools, health insurers, Medi-Cal providers, and healthcare providers throughout the state who can educate consumers.

b) Post the curriculum on the websites of the relevant state departments and promote its availability through issuance of a press release and other public notice activities;

c) Develop and disseminate suggested strategies, possibly unique to each intermediary, to encourage consumers to attend presentations based on the curriculum.

d) Create a web-based interactive version of the curriculum that will be posted on websites of designated state entities and require those entities to promote the availability of the curriculum via no or low cost methods, such as press releases, faxes and email.

e) Coordinate this activity with the efforts to educate health care professionals about medication errors and prevention issues in Goal 5, Recommendation 10.

6.3 Recommend that the California Medical Board and the California Board of Pharmacy encourage physicians and other prescribers to post notice in their offices informing consumers of their right to know, and the benefits of understanding the name of any medication prescribed and the indication(s) and instructions for use, in addition to their right to consult with a pharmacist.

Recommendation 7

Develop and implement strategies to increase the involvement of public and private sector entities in educating consumers about improving medication safety and effectiveness.

Methods

7.1 Require the California Board of Pharmacy and/or the Department of Consumer Affairs to collaborate with a cross-section of public and private sector entities, including prescription drug plans, health care service plans, health insurers, and/or mail-order pharmacies, to support and/or undertake efforts to educate consumers about safe medication use. Use legislative and regulatory means to ensure a joint effort is made by all agencies that regulate these entities to collaborate in these efforts.

C. Provider Standards and Incentives

Background:

The drug consultation given by a pharmacist to their patient, or the patient's agent, can be a powerful means for educating consumers about drug safety. However, current law regarding pharmacists' consultation contains only the minimal requirements that were established in the early 1990s. In light of the substantial changes the State's health care system has undergone since that time, a re-examination of the pharmacist's consultation requirement is in order.

The Panel recommends that the Board of Pharmacy establish new pharmacist consultation standards that would provide greater benefit and protections to the public. Consistency should be a key component of the new standards, and they should take into account the economic and workforce conditions that impact the ability of pharmacists to provide this essential service.

Medication therapy management programs (MTM) provide another important tool in avoiding medication errors. The purpose of these programs is to evaluate whether prescribed medications are yielding desired results and, if not, to recommend or implement adjustments to therapies to maximize outcomes. To properly protect consumers, MTM programs should meet minimum standards for provider qualifications and program design.

Goal 4: Improve the quality and availability of pharmacist-patient medication consultation.

Recommendation 8

Help ensure quality and consistency of medication consultation provided by pharmacists within and among pharmacies.

Methods

8.1 Require the California Board of Pharmacy to review and, as needed, revise current regulations regarding patient consultation to focus on what would actually be useful to patients to help maximize their therapeutic outcomes and take their medications safely and effectively.

The California Board of Pharmacy shall invite stakeholders, including consumer representatives, to collaborate to develop minimal standards for required consultation. These deliberations should consider factors that reflect the current conditions of the business and healthcare environments, various types of pharmacy practices and practice settings (e.g. community, mail-order, extended care), and the "learning environment" available in those settings for providing consultation. The standards should be applied equally to all providers or entities dispensing medications to California consumers, including non-resident pharmacies.

Nothing in consideration of these standards shall preclude pharmacists from being paid for services that exceed these minimal standards.

These standards should address, at a minimum:

a) Encouraging or providing incentives to pharmacists for providing patient medication consultation with prescription renewals, when appropriate.

b) Re-examining the circumstances involved with patients' refusal of consultation, and what type of documentation is required, if any, for patients who refuse consultation. The Panel strongly emphasized that the following factors be considered as part of the re-examination process: (1) prohibiting any pharmacy employee from asking a patient or patient's agent if he/she wants pharmacist prescription consultation (i.e. no "screening" questions) and (2) requiring that the patient communicate the refusal of consultation directly to a pharmacist.

Recommendation 9

Establish standards for medication therapy management (MTM) programs and create incentives for their implementation and ongoing use by pharmacists and other healthcare providers

Methods

9.1 Require the California Board of Pharmacy to identify best practices and to develop evidence-based standards of care for MTM programs, and to disseminate these to known MTM providers, the Department of Health Services, Department of Managed Health Care, Department of Insurance, the Managed Risk Medical Insurance Board, CalPERS, California Medical Board, and to applicable professional and healthcare associations (e.g. California Medical Association, California Pharmacists Association, California Association of Health Plans).

9.2 Require the Department of Health Services, Department of Managed Health Care, Department of Insurance, Managed Risk Medical Insurance Board, California Medical Board, Board of Registered Nursing, Board of Pharmacy, and appropriate private sector entities to develop and implement strategies to incentivize payers, pharmacists and other healthcare providers to implement and routinely use MTM standards of care. These public entities shall report their respective related activities to the Assembly and Senate Health Committees, and to notify the public by posting descriptions of their activities and/or any findings on their websites and notifying the public and media by issuing one or more press releases.

9.3 Consistent with the standards developed in this recommendation, require the Department of Managed Health Care, the Department of Health Services and the Department of Insurance to allow health plans, health insurers, and Pharmacy Benefit Managers flexibility in methods of implementing MTM programs, including via face-to-face interaction, call center advice lines, and secure e-mail communication.

9.4 Encourage state-funded programs (e.g., Medi-Cal and CalPERS) to establish financial and other incentives for healthcare providers and patients improving drug therapy compliance, including cases of over-use (including therapeutic duplication) and under-use of prescription medication.

D. Healthcare Provider Training and Education

Background:

Good communication skills are essential in the current health care environment, and are a key tool in reducing medication errors. Pharmacists and other health care professionals must take into account their patients' language skills and cultural characteristics in order to effectively convey essential information to them. There is therefore a need to educate prescribers and pharmacists concerning improved ways to help their patients understand the proper use of medications, the importance of complying with their treatment regimen, and the need to report any problems to their prescriber or pharmacist.

Considering the ever increasing numbers of patients who have conditions that can be managed with therapies that are frequently long-term and involve the use of multiple medications, healthcare providers are also likely to benefit from more training and education around the intricacies of medication therapy management (MTM). While much of this information is already an integral component of pharmacist training, many of the skills needed to apply it are distinct from a pharmacist's traditional dispensing role. Consequently some pharmacists may have a need to obtain other types of training as well.

Goal 5: Improve education and training of pharmacists and other health care professionals about medication errors and prevention methods.

Recommendation 10

Create training requirements for pharmacists and other healthcare professionals that address medication safety practices and related programs, including medication consultation and medication therapy management programs.

Methods

10.1 Require that the licensing boards for relevant health care professionals (e.g., pharmacists, physicians, nurses, dentists and optometrists) establish specific requirements for training/education about medication safety practices (e.g., medication error reduction strategies, patient medication consultation, and medication therapy management methods) as part of licensure, certification, and/or continuing education requirements. Further, require these boards to report their findings and plans for improving their requirements in this regard to the appropriate cabinet-level position, the Assembly and Senate Health Committees, and the public through posting of the report on their websites and issuing one or more press releases.

10.2 Encourage the colleges, universities, and schools that provide degree programs for health care professionals (e.g., pharmacists, physicians, nurses, dentists, optometrists, pharmacy technicians) to establish and maintain specific curricular requirements about medication safety practices (e.g., medication error reduction strategies, patient medication consultation, medication therapy management methods).

10.3 Encourage employers of healthcare providers, as well as the healthcare professional associations (e.g., the California Medical Association, California Pharmacists Association, California Society of Health System Pharmacists, and California Nurses Association), to establish and maintain ongoing training and educational activities for their respective constituencies about medication safety practices (e.g., medication error reduction strategies, patient medication consultation, medication therapy management methods).

10.4 Require that the licensing boards of relevant healthcare professions (e.g. pharmacists, physicians, nurses, dentists and optometrists) evaluate the effectiveness of their respective licensing requirements (e.g. board examinations) in determining a licentiate's ability to communicate medication-related information and instructions to consumers in a manner that reduces the risk of medication errors related to patient misunderstanding. Further, require these boards to report their findings and plans for improving their requirements in this regard to the appropriate cabinet-level position, the Assembly and Senate Health Committees, and the public through posting of the report on their websites and issuing one or more press releases.

E. Research about Prevalence & Occurrence of Medication Errors

Background:

Obtaining information about the incidence, nature and frequency of medication errors in the community setting is challenging. Most research on medication errors has been conducted in hospitals, even though the drugs administered in inpatient settings represent a very small proportion of medications dispensed. Indeed, there is comparatively little academic research available regarding medication errors occurring in the community setting. While it appears that this situation is beginning to improve, a greater emphasis on research related to medication errors in the community setting is definitely warranted.

Goal 6: Increase evidence-based information about the nature and prevalence of medication errors available to policy-makers, pharmacists, consumers, and other interested parties.

Recommendation 11

Establish and support efforts to collect data regarding the nature and prevalence of medication errors and prevention methods for reducing errors, especially focused on persons at high risk for medication errors and on community, ambulatory and outpatient settings.

Methods

11.1 Require by legislation, regulation, joint legislative resolution, and/or issuance of a Governor's Executive Order that the California Board of Pharmacy establish an agreement with a private sector organization, such as the Institute of Safe Medication Practices (ISMP), to establish a pilot project to collect and analyze data about the nature and prevalence of medication errors at California community-based pharmacies.

Require that the cost of this project to the State be negligible.

Require the California Board of Pharmacy to share data about medication errors reported to it with the entity responsible for implementing this recommendation and that the Board collaborate with the entity responsible for implementing this recommendation to promote the project to consumers, pharmacies and providers. The project should ensure that:

a) Prescribers, pharmacists and consumers may voluntarily and confidentially report errors to the ISMP or other responsible entity.

b) The entity responsible for implementing this recommendation report annually to the California Board of Pharmacy, the California Medical Board and the Senate and Assembly health committees, and that these reports indicate if an error occurred either under the auspices of a health care facility or in a community setting (i.e., retail pharmacy or private residence) and the severity of the error (i.e., if it resulted, contributed or may have been associated with death, hospitalization or serious injury).

c) The information collected and reported by this project should not be used in any legal proceedings against prescribers and/or pharmacists.

d) The project be designed to minimize conflict with existing systems that are used to collect data from pharmacies as part of their current California Board of Pharmacy Quality program.

e) Efforts to inform consumers about this project include information handed out at pharmacies, on medication information sheets, and with related public education campaigns.

f) The California Board of Pharmacy and the Medical Board post the reports produced by this project on their respective websites.

g) Persons reporting errors to the entity responsible for implementing this recommendation be informed of their right to also report errors to the California Board of Pharmacy and the benefits of doing so.

F. Other Topics to be Addressed

Background:

The many obstacles that pharmacists face in providing drug consultation to their patients as required by law are exacerbated by the lack of a payment system that would compensate them for the time and expense associated with performing these mandated tasks. Before additional duties can be imposed on pharmacists practicing in the outpatient setting, changes to the health care financing reimbursement system must occur. This issue was beyond the charge of the Panel, but it was recognized to be an issue that must be addressed hand-in-hand with other practice enhancement efforts in order to assure success in the current and future marketplace and workforce environments.

Goal 7: Develop strategies designed to increase incentives for pharmacists to offer and provide medication consulting and medication therapy management services to consumers.

Recommendation 12

Convene a panel of stakeholders to identify and propose specific actions and strategies to overcome barriers to qualified pharmacists being recognized and paid as healthcare providers.

Methods

12.1 The Legislature should convene a panel of stakeholders representing California pharmacists, healthcare providers, consumer groups, payers, health plans and other perspectives to hold a series of public meetings and issue recommendations addressing the reimbursement of pharmacists for non-dispensing services.

Reimbursement for medication consultation should be based on standards of care (see recommendations and discussion under Goal 4). If such standards have not been adopted at the time that the panel is convened, then the panel should make recommendations to the California Board of Pharmacy about development of the standards.

In considering recommendations for reimbursing pharmacists for patient medication consultations, the panel should weigh factors based on patient-specific information, including, but not limited to time spent providing the consultation or complexity of the consultation (the number of medications taken by the consumer, the consumer's compliance challenges, language, literacy or translation needs, or patient diagnosis). Additionally, the panel should take into account the most current thinking on this subject from relevant regional or national entities such as the US Centers for Medicare and Medicaid Services, Quality Improvement Organizations, and pertinent payer and provider organizations.

SECTION III: APPENDICES

Appendix A: Panel Meeting Dates and Speakers

The Medication Errors Panel held 12 meetings in Sacramento, the first on May 5 and the last on November 16, 2006. Presentations were made to the panel by persons listed below on the dates indicated.

May 5

- Senator Jackie Speier, Panel Chair and Author of SCR 49
- Senator Sam Aanestad, Panel Member
- Lynn Rolston, CEO of CA Pharmacists Association
- Robert MacLaughlin, Aging and Long Term Care, Senate Health Subcommittee
- John Gilman, Assembly Health Committee
- Dawn Adler, Office of Assemblymember Betty Karnette
- Sang-ick Chang, M.D., San Mateo County Medical Center
- Michael J. Negrete, Pharm.D., Pharmacy Foundation of CA

May 19

- Eleanor M. Vogt, R.Ph., Ph.D., Health Sciences Clinical Professor and 2004 – 2005 Presidential Chair, UC San Francisco School of Pharmacy
- Patricia Harris, Executive Director, Board of Pharmacy
- John Gallapaga, SmartRx for Seniors
- Lisa Chan, Office of Assemblymember Wilma Chan

June 2

- Michael Cohen, R.Ph., MS, FASHP, founder of the Institute for Safe Medication Practices (ISMP)
- Patricia Harris, Executive Director, CA Board of Pharmacy
- Dave Thornton, Executive Director, CA Medical Board
- Dr. William Soller, PhD, Executive Director, Center for Consumer Self-Care, University of CA, San Francisco

June 16

- Bill G. Felkey, Professor, Pharmacy Care System, Auburn University, Alabama
- David Murphy, SureScripts
- Pam Bernadella, RPh, Manager, Pharmacy Professional Services, Target Corporation, Minnesota

June 30

- Victoria Bermudez, RN, CA Nurses Association
- Lori Hack, Interim CEO, CA Regional Health Information Organization
- Sharon Youmans, Pharm.D, MPH, Professor of Clinical Pharmacy, University of CA, San Francisco

August 11

- Dr. Robert E. Lee, Jr., Eli Lilly, and U.S. Food and Drug Administration Trademark Focus Group Member
- Tom Williams, CEO, Integrated Healthcare Association
- David Murphy, SureScripts and Get Connected CA
- Carmella Gutierrez, Lumetra
- Peter Boumenot, Lumetra, Electronic Health Records Implementation Consultant

August 25

- Paul Tang, MD, Vice President, Chief Medical Information Officer, Palo Alto Medical Foundation, Sutter Health

- Susan L. Ravnan, Pharm. D., Associate Professor, University of The Pacific Thomas J. Long School of Pharmacy and Health Sciences; CA Society of Health System Pharmacists representative

September 15

- Robert Friis, PhD, California State University Long Beach, Department of Health Sciences Chair, and American Public Health Association Southern California Chapter President
- Gurbinder Sadana, MD, FCCP - Director of Critical Care Services, Pomona Valley Hospital Medical Center; California Medical Association representative

September 29

- Panel committees begin work of drafting recommendations for final report

October 13

- J. Kevin Gorospe, Pharm. D., Chief, Medi-Cal Pharmacy Policy Unit
- Loriann De Martini, Pharm.D., Chief Pharmaceutical Consultant, Licensing and Certification Division, Department of Health Services

November 2

- Senator Jackie Speier, Panel Chair, met with the Panel to discuss major issues, and Panel's progress on developing final recommendations

November 16

- Final meeting of the Panel to discuss recommendations

Appendix B: Prior Legislative Efforts to Address Medication Safety

The following legislation relevant to the objectives of the Panel has been enacted:

- SB 1339 (Figueroa) became law in 2000 and requires pharmacies to establish quality assurance programs to reduce frequency of medication errors. Every pharmacy is required to have a system of tracking and assessing errors so that the proper steps can be taken to reduce the chance of a reoccurrence. It exempts any documents generated by the program from legal discovery proceedings.

- SB 1875 (Speier), 2000, requires hospitals and surgical centers to develop medication error reduction plans and submit the plans to the Department of Health Services. In order for a health facility or clinic to obtain a license it must complete a plan to eliminate or substantially reduce medication error by 2005.

- SB 292 (Speier) 2003, requires labels on pill bottles to include a written description of the drug that was prescribed, including its color, shape, and any identification code appearing on the tablets or capsules. (This bill initially sought to have a color image of the pill or tablet printed on the bottle label.)

- SB 151 (Burton), 2004, requires that tamper-resistant security forms be used for nearly all *written* prescriptions for controlled substances (Schedules II-V). This pre-printed and numbered form must contain at least ten security features and replaces the Schedule II triplicate prescription forms. Pharmacies must report Schedule III prescriptions to the CURES program.

There were six bills before the legislature during the 2005-2006 session that had objectives relevant to medication safety. They were the following:

- AB 71 (Chan) would have established the Office of the California Drug Safety Watch to administer a database of information about the safety and effectiveness of highly advertised prescription drugs. The database was to include reports of adverse drug reactions (ADRs) which would have been accessible to health professionals and the public. This bill is inactive.

- AB 657 (Karnette) would have required that the purpose or indication of a medication be listed on the prescription label if a prescriber had written it on the prescription. This bill is inactive.

- SB 1301 and SB 380 were both introduced by Senate Elaine Alquist in 2005. SB1301 was chaptered September 29, 2006 and requires acute care facilities to report ADRs to the Department of Health Services within five days of the occurrence. SB 380 originally contained a mandatory reporting requirement to the federal Food and Drug Administration for all serious ADRs, but was amended to address a non-related issue.

- SB 329 (Cedillo) 2005, would have established the California Prescription Drug Safety and Effectiveness Commission within the California Health and Human Services Agency. The Commission would request assistance from a unit of the University of California and be a repository of information about prescription drug safety and effectiveness. In February 2006, this bill was returned to Secretary of Senate pursuant to Joint Rule 56.

- AB 72 (Frommer) 2005, would have established the Patient Safety and Drug Review Transparency Act in order to ensure that information regarding clinical trials of prescription drugs is available to the public, physicians, and researchers. On January 31, 2006, this bill died on the inactive file.

Prescription for Improving Patient Safety: Addressing Medication Errors

An Executive Summary of the The Medication Errors Panel Report

Pursuant to California Senate Concurrent Resolution 49 (2005)

About the Medication Errors Panel:

Recognizing the significant and growing public health concern of medication errors, in 2005 Senator Jackie Speier authored Senate Concurrent Resolution (SCR) 49, sponsored by the California Pharmacists Association. This resolution, adopted September 14, 2005, called for the creation of an expert panel to study the causes of medication errors in the outpatient setting and to recommend changes to the healthcare system that would reduce errors associated with prescription and over-the-counter medication use.

The Medication Errors Panel, assembled in 2006, consisted of two Senators, two Assembly members and 13 persons representing academia, consumer advocacy groups, health professions (medicine, nursing, public health and pharmacy), health plans, the pharmaceutical industry, and community pharmacies. Throughout 2006, Panel members gave a tremendous effort to this study and met at the state capitol 12 times to hear and discuss testimony from 32 invited speakers who included many widely respected state and national leaders in the fields of pharmacy practice, medicine, medical technology, healthcare regulation, academia, and the pharmaceutical industry.

The following is the Executive Summary of the Panel's report complete with its consensus recommendations.

The Problem of Medication Errors

A medication error is any preventable event occurring in the medication-use process, including prescribing[1], transcribing, dispensing, using and monitoring, that results in inappropriate medication use or patient harm. These errors and their consequences present a significant public health threat to Californians.

While most consumers and healthcare providers do not often associate poor health outcomes with adverse drug events – frequently the result of medication errors – the human and financial costs of the problem are staggering.

The most recent estimate of costs associated with drug-related morbidity and mortality in the US exceeds $177 billion per year.[2] Amazingly, this amount is significantly greater than the amount actually spent on prescription drugs during the same year. In terms of patient harm, the Institute of Medicine projects that at least 1.5 million Americans are sickened, injured or killed each year by medication errors.[3] Extrapolating these figures to California suggests that on an annual basis, the problem costs our state $17.7 billion and causes harm to 150,000 Californians.

Perhaps the most concerning aspect of these errors is that the tremendous human and financial costs are not the result of some serious disease, but rather, well-intentioned attempts to treat or prevent illness.

Reducing Errors through a "Systems Approach"

Testimony provided to the Panel indicated that efforts to address errors are best targeted not at a particular group of individual "wrong doers," but rather at faulty systems, processes, and conditions that either lead people to make mistakes or fail to prevent them. Consequently the Panel took a "systems approach" for studying the problem and developing its recommendations.

After spending considerable time examining each part of the medication-use process – prescribing, dispensing, using (administering/self-administering) and monitoring – and the inter-relationships of each component, the Panel identified four key medication-use systems/ processes and three key stakeholder groups which served as the focus of its recommendations.

Key Processes and Stakeholders

The four key processes which the Panel believes could be better designed to reduce and prevent medication errors are those related to:

1) **The transcription and transmission of prescriptions** (i.e. the methods prescribers use to document a prescription order and communicate that order to the pharmacy where it will be filled).

2) **The education of the consumer** regarding the purpose of the treatment, the effective use of the medication, and the monitoring of signs and symptoms that may indicate efficacy or toxicity.

3) **Healthcare provider payments and incentives** which can directly or indirectly influence providers to pursue behaviors designed to reduce medication errors.

4) **Healthcare provider training and licensure** which could foster a better understanding among providers about the seriousness of medication errors and the behaviors to adopt that will reduce them.

The three key stakeholder groups which the Panel believes will be critical in affecting the necessary changes to these processes are:

1) **Consumers and consumer oriented organizations** such as the California Department of Consumer Affairs; advocacy organizations (e.g. AARP, American Heart Association); community-based organizations; and private and public foundations.

2) **Healthcare providers and related organizations** such as academic institutions, professional societies and advocacy groups, and provider licensing/oversight Boards.

3) **Healthcare purchasers, payers, regulators and related organizations** such as the State of California, its Department of Health Services and the Medi-Cal program; private purchasers of health care such as employers; commercial insurance companies which administer health benefits for both public and private sector purchasers; the California Departments of Insurance and Managed Health Care which regulate these insurance companies; pharmacy benefit managers which focus specifically on the administration of pharmacy benefits; and of course, the Legislature and Administration of the State of California which possess the potential to influence and/or establish accountability for these groups.

Based on the analysis of these four key processes and three key stakeholder groups, the Panel developed 11 consensus recommendations within five subject areas, and a twelfth recommendation to further consider and address issues that went beyond the scope of the Panel's purpose.

Recommendations

A. **Communication Improvements,** with an emphasis on improving the quality and accuracy of communications between prescribers, pharmacists and patients. Specific recommendations are:

1) Improve legibility of handwritten prescriptions, and establish a deadline for prescribers and pharmacies to use electronic prescribing.

2) Require that the intended use of the medication be included on all prescriptions and require that the intended use of the medication be included on the medication label unless disapproved by the prescriber or patient.

3) Improve access to and awareness of language translation services by pharmacists at community pharmacies and encourage consumers to seek out pharmacists who speak their language and understand their cultural needs.

4) Promote development and use of medication packaging, dispensing systems, prescription container labels and written supplemental materials that effectively communicate to consumers accurate, easy-to-understand information about the risks and benefits of their medication, and how and where to obtain medication consultation from a pharmacist.

B. **Consumer Education** to increase consumer awareness regarding the proper use – and dangers of misuse – of prescription and over-the-counter medications. Specific recommendations are:

5) Identify and disseminate information about best practices and effective methods for educating consumers about their role in reducing medication errors.

6) Establish an on-going public education campaign to prevent medication errors,

targeting outpatients and persons in community settings.

7) *Develop and implement strategies to increase the involvement of public and private sector entities in educating consumers about improving medication safety and effectiveness.*

C. **Pharmacy Standards and Incentives,** with a focus on information and medication consultations given by pharmacists to their patients as a means of educating consumers about drug safety. Specific recommendations are:

8) *Help ensure quality and consistency of medication consultation provided by pharmacists within and among pharmacies.*

9) *Establish standards for Medication Therapy Management (MTM) programs and create incentives for their implementation and ongoing use by pharmacists and other healthcare providers.*

D. **Training and Education for Healthcare Providers** on various medication safety practices. The specific recommendation is:

10) *Create training requirements for pharmacists and other healthcare professionals that address medication safety practices and related programs, including medication consultation and medication therapy management programs.*

E. **Research,** with a focus on obtaining information about the incidence, nature, and frequency of medication errors in the community setting. The specific recommendation is:

11) *Establish and support efforts to collect data regarding the nature and prevalence of medication errors and prevention methods for reducing errors, especially focused on persons at high risk for medication errors and on community, ambulatory and outpatient settings.*

In addition to these five subject areas, the Panel identified a sixth that needs to be addressed but which it determined was beyond its scope. This issue relates to the many obstacles that pharmacists face in providing drug consultation to their patients which encompasses a variety of factors such as manpower shortages and the lack of payment systems to cover the time and expense associated with these tasks. Before additional duties can be imposed on pharmacists practicing in outpatient settings, the Panel recognizes that these issues must be addressed. Therefore the Panel put forth a twelfth recommendation:

12) *Convene a panel of stakeholders to identify and propose specific actions and strategies to overcome barriers to qualified pharmacists being recognized and paid as healthcare providers.*

Acknowledgements

This project has benefited from the generous contributions of many individuals and organizations. In particular the Panel would like to thank former Senator Jackie Speier who authored the resolution; Lynn Rolston of the California Pharmacists Association which sponsored SCR 49 (2005); Judith Babcock of the Pharmacy Foundation of California which managed funding for the Panel and arranged for administrative support; the Kaiser Family Foundation and California HealthCare Foundation which funded the Panel; Sandra Bauer, Michael Negrete and Ronald Spingarn who provided staff support for the Panel; and of course all of the Panel members listed on the following page with special thanks to Carey Cotterell for helping to write this report.

End Notes and References

[1] While the Panel identified drug and dose selection as a process (i.e. prescribing) where errors can occur, its analysis and recommendations were focused on the areas of the medication-use process that occur *after* the point where prescribers consciously make such decisions.

[2] Ernst FR, Grizzle AJ. Drug-related morbidity and mortality: updating the cost-of-illness model. J Am Pharm Assoc 2001;41:192-9.

[3] Institute of Medicine (IOM). (2007). *Preventing medication errors: Quality chasm series.* P. Aspden, J. Wolcott, J. L. Bootman, & L. R. Cronenwett (Eds.). Washington, DC: The National Academies Press.

MEDICATION ERRORS PANEL MEMBERS

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Professor and Chair, Health Sciences Department, California State University Long Beach (representing a public health organization*)

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Testimony before the California State Board of Pharmacy
Legislation and Regulation Committee

Tuesday, April 3, 2007; 9:30 a.m. - 1:00 p.m.
Communication and Public Education Committee

Tuesday, April 3, 2007; 1:30 p.m. - 3:30 p.m.
Department of Consumer Affairs

First Floor Hearing Room
1625 North Market Boulevard
Sacramento, CA 95834

Fred S. Mayer, R.Ph., M.P.H.
President, PPSI

Thank you for inviting me to testify in today's Legislation and Regulation Committee and the Communication and Public Education Committee meetings.

I am Fred Mayer, R.Ph., M.P.H., President of Pharmacists Planning Service, Inc. (PPSI) a 501 C (3) nonprofit public health, consumer, pharmacy education organization. I have been a practicing pharmacist for over fifty years licensed in the State of California. I am also Past President of the California Public Health Association.

I would like to spend my time in responding to what needs to be done to fix the prescription error issue. There are four basic pieces of legislation which CPhA would like considered as a packet for fixing the 150,000 errors and deaths which have been documented by SCR 49 (Senator Jackie Speier), Prescription Error Study, as follows:

The four bills that concern the label and the labeling process are: SB 472 Corbett (label requirements), which PPSI is in favor of; AB 1276 Karnette (prescription containers and labels) which PPSI is in favor of; AB 1399 Richardson (prescription labels), which PPSI is in favor of; and AB 851 Brownley (informational inserts), which PPSI is in favor of. The other bill we should discuss is SB 966 by Simitian, which is a great idea but must be done carefully and done right.

PPSI's concerns, which were articulated to the California Board of Pharmacy in its November 30, 2006 testimony and again on December 13, 2006 to the Medicare Consumer Advocacy Group and to CMS at that same meeting, are as follows:

1. We've gone from 2 billion prescriptions in 2003, to 4 billion prescriptions in 2007. This is an overload on pharmacists.

2. The California Board of Pharmacy, under President Tom Nelson and Sandra Bauer, determined that pharmacists' counseling could eliminate 50% of all errors.

3. Since many PBMs, PDPs, HMOs and managed care organizations require a 30 day supply only for pharmacists, this must be changed for all maintenance drugs to a 90 day supply through legislation.

4. This would reduce the 4 billion prescriptions back to 2 billion and make time available for pharmacists to counsel, look at the computer screen and do cognitive services.

5. A few years ago, NACDS put out a White Paper on how pharmacists spend their time in the workplace. Approximately 73% of the pharmacists' time is spent on processing orders and prescriptions, 9% on managing inventory, 5% on processing pharmacy administration claims and 13% on other miscellaneous activities (Exhibit 1).

6. It has been documented there are over 700,000 prescription, OTC and herbal errors where patients need to visit hospital emergency rooms. (Exhibit 2) This could be fixed by legislation to reimburse pharmacists for counseling patients.

7. 107,000 folks are dying per year (Lucien Leppe, M.D. Study from Harvard) from taking the wrong medicine, switching drugs and in general failure to counsel, etc. (Exhibit 3)

8. At the November 30th Board of Pharmacy hearing, PPSI proposed twelve issues to reduce prescription drug costs. We have not seen anything come out of this November 30th hearing. We have presented much of this material again today (Exhibit 4).

9. In order for the number of prescription errors to be reduced, we must have transparency by PBMs, PDPs, HMOs & managed care organizations on how drug products are being selected for their formularies. This is especially important for the 43 million Medicare patients who are being switched from Rx to Rx, depending on kickbacks and rebates from the drug companies causing mass confusion in the marketplace (Exhibit 5).

10. Evidenced-based medicine and P & T Committees must be mandated. The California Board of Pharmacy must put new legislation into place and CPhA in order to give patients and consumers the best medicine available based on evidenced-based medicine and not what is best for the corporate bottom line.

11. There is no one in charge of oversight of the PBMs, PDPs, HMOs, & managed care groups, including CMS. SOMEONE HAS TO HAVE OVERSIGHT AND BE WATCH DOGS FOR THESE FOLKS WHO ARE RAPING THE PUBLIC (Exhibits 6 - 7 "Medco Fined $155 Million by Federal Government").

12. PPSI has petitioned FDA and FTC regarding print size of the direct-to-consumer advertising as the print size is so small on DTC, it is referred to as "mouse print", it is illegible and unreadable.

13. Black box warnings for 80 prescription drugs must be kept out of the kiosks. Pharmacists should be mandated to warn all patients per FDA black box instructions about these medications, side effects and adverse drug issues.

Thank you for allowing me to testify at the Legislation Regulation and the Communication and Public Relation Committee meetings.

2007 Prescription Drug Labeling: pending legislation			
Bill #	Author	Description	Sponsors
AB 851	Brownley	Would require pharmacists to include a large print insert when dispensing medications that pose a substantial risk when taken with alcohol, other medications, or other over-the-counter drugs. Notes: There is a lack of information on concordance in warning labels. Experts view warning labels as a problem with serious implications that should be regulated.	
AB 1276	Karnette	Would require that the intended purpose of a prescription drug be printed on the label if the prescribing agent indicates the intended use on the prescription order form. Notes: Ran last year as AB 657, and was supported by CA Pharmacists Association and sponsored by CSL on the grounds that printing the intended use of the drug would help to reduce medication errors. Opposed by CMA last year on the grounds that printing the intended use would put a patient's privacy at jeopardy. Current statute provides that the condition be included on the label if requested by the patient.	Last year: California Senior Legislature
AB 1399	Richardson	Would require a prescription drug label to be readable by an assistive listening device if requested by a blind or visually impaired patient. Notes: There is debate in the visually impaired community regarding the effectiveness and usefulness of assistive listening devices. Other advocates for the visually impaired are concerned that this bill would mandate the type of technology pharmacists can use when printing labels and hinder pharmacists.	Possibly: National Federation of the Blind
SB 472	Corbett	Would standardize the format of prescription drug labels and provide that the label be able to be translated into another language if requested by the patient.Notes: OuRX members co-sponsor bill.	Gray Panthers, LCHC, Senior Action Network

SB 472 provisions on process, non-language standards, and implementation

Process

A prescription drug label panel shall be appointed to work with the Board of Pharmacy. The panel shall be appointed by the Speaker, the Senate President, and the Governor. Each shall appoint five. A majority of their appointees shall be from groups representing seniors and groups representing those with special issues regarding language and cultural competency in the use of prescription drugs.

To work with the panel, the Board of Pharmacy shall delegate its members as it sees fit. The Board of Pharmacy shall staff the panel.

Legibility and safety standards

On the recommendation of the panel, the Board of Pharmacy shall adopt a standardized label for prescription drug containers.

The label shall be developed so that it:

(a) It is readable for prescription drug users.
(b) It describes the contents of the container so that prescription drug users with a 4th grade reading level can understand it.
(c) It displays necessary information about properly taking the containers' contents so that prescription drug users with a 4th grade reading level can understand it.
(d) It displays mandated warnings about the containers' contents so that prescription drug users with a 4th grade reading level can understand it.
(e) A translation or interpretation of the directions for use can be obtained at the pharmacy dispensing the drug.

The panel shall also provide that the implementation of the standardized label shall be affordable for independent pharmacies.

Implementation

The panel shall begin meeting by October 1, 2007.

The Board of Pharmacy shall adopt a standardized label by September 30, 2008. It shall report to the appropriate committees of the Legislature on that date.

California pharmacies shall begin using the standardized labels on January 1, 2009.

Medication errors take grim toll, study says

Mistakes sicken, kill 150,000 in state; steps urged to cut confusion over drugs

By Steve Geissinger
MediaNews

SACRAMENTO — Medication errors sicken or kill 150,000 Californians and cost more than $17 billion annually, says a yearlong study by a new state board, created under a Bay Area lawmaker's bill.

The Medication Errors Panel issued a dozen suggestions to reduce confusion over prescriptions, which leads to patients taking an incorrect medicine that can sharply worsen their condition or taking different kinds of pills that should not be combined and cause dangerous, unintended side effects.

The problem is standing out now more in communities — between doctors, pharmacies and patients — than it once did in hospitals, which are operating under new, strict laws.

Gov. Arnold Schwarzenegger's aides pointed to the report, released Tuesday, as further justification for his health-care reform proposal, which would guarantee health care for every uninsured Californian. Officials said some changes — simply getting all physicians and pharmacies to electronically transmit prescriptions — already are part of the governor's program.

"It's really an outrage that actions, such as those recommended by the panel, have not already been taken," said former Sen. Jackie Speier, a Peninsula Democrat who sponsored the

See Medication, page A5

MEDICATION: Study says mistakes have caused illness, deaths

From page A1

bill to establish the panel for the California Pharmacists Association.

"The recommendations will save the lives of thousands of Californians and should be incorporated into legislation without delay," Speier said in a statement.

The panel, made up largely of medical experts, held 12 hearings where they heard from doctors, pharmacists, government regulators and others.

The medical error board's other suggestions include adding the purpose of a drug to the bottle label, better educating consumers, urging patients to listen to advice about potential drug conflicts, providing better training to pharmacy workers and bolstering government oversight.

Sen. Sheila Kuehl, a Santa Monica Democrat who chairs the Senate Health Committee, vowed to work toward making the suggestions into law.

Kuehl said that even "simple mistakes" can have "devastating consequences," especially those involving children.

Representatives of seniors' organizations said the same is true for the elderly.

In the spirit of the panel's recommendations, Sen. Ellen Corbett, D-San Leandro, already is sponsoring SB472, which would require pharmacies to issue labels in the patient's language and regulate the size of printing on pill bottles.

"Approximately 46 percent of American adults cannot understand the label on their prescription medications," according to Corbett's legislation.

"Ninety percent of Medicare patients take medications for chronic conditions and nearly one-half of them take five or more different medications," Corbett also says in her bill.

The panel's report this week came as a group that sets standards for the drug industry found young children are the most likely victims of medication mistakes nationally and a nonprofit foundation unveiled a Web site where patients rate hospitals.

It also came as Schwarzenegger is working toward approval of a wide-ranging universal health care proposal.

The governor already has signed an executive order aimed at achieving complete electronic health data exchanges in the next decade, aides said.

"No one should suffer from errors in the improper prescribing, dispensing or use of medication, or suffer from unnecessary health care-acquired infections," said Kim Belshe, the secretary of the Heath and Human Services Agency.

"For this reason, Gov. Schwarzenegger's reform proposal calls for dramatic change to prevent not only medication errors, but medical errors as well," she said in a statement.

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Medication errors kill, sicken many

By Steve Geissinger
MediaNews Sacramento Bureau

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Medication errors targeted in report ...

■ Continued from Page 1A

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SIDNEY M. WOLFE, M.D., EDITOR

March 2007 ◆ VOL. 13, NO. 3

Adverse Reactions to Cough and Cold Meds Sent 1500 Babies to the Emergency Room in 2004, 2005

The Centers for Disease Control and Prevention (CDC) found that children under age 2 are at risk for illness or even death if they are given prescription or over-the-counter cough and cold medicine.

More than 1,500 children under two were treated in emergency rooms across the United States for overdoses and other adverse reactions associated with the use of cough and cold products in 2004 and 2005, according to a new CDC report that was published January 12 in the agency's weekly newsletter, *Morbidity Mortality Weekly Report*. The CDC report is available online at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5601a1.htm.

In the report, the CDC made the following recommendations about administering cough and cold medications to children under 2 years of age:

> Caregivers and clinicians should be aware of the risk for serious illness or fatal overdose from administration of cough and cold medications to children aged [less than] 2 years. Caregivers should only administer cough and cold medications to children in this age group when following the exact advice of a clinician. Clinicians should be certain that caregivers understand 1) the importance of administering cough and cold medications only as directed and 2) the risk for overdose if they administer additional medications that might contain the same ingredient. Caregivers should always inform their health-care providers of all medications they are administering to a child.

In response to this report, the CDC and the National Association of Medical Examiners (NAME) investigated and identified three deaths in infants under six months of age. Coroners or medical examin-

continued on page 18

COUGH AND COLD MEDS,
from page 17
ers determined that the cause of death in the three infants was ingestion of cough and cold preparations.

The three infants who died ranged in age from 1 to 6 months. They all had high levels of the nasal decongestant pseudoephedrine (SUDAFED) in their blood. (We list pseudoephedrine as a Do Not Use drug for children and adults because it can raise heart rate and blood pressure.)

Two of the infants received a single pseudoephedrine-containing drug, one prescription and one over-the-counter. The third infant had been given both a prescription and an over-the-counter cough and cold combination drug – each containing pseudoephedrine – at the same time.

Both of the infants who had been given a prescription had ingested a drug containing the antihistamine carbinoxamine.

There were also detectable blood levels of the cough suppressant dextromethorphan and acetaminophen (TYLENOL), the popular pain and fever reducing drug, in the two infants who received over-the-counter medication.

The CDC made its estimate of emergency room visits with a national tracking system called the National Electronic Injury Surveillance System – Cooperative Adverse Drug Event Surveillance (NEISS-CADES). This system was developed by the CDC, the Food and Drug Administration (FDA) and the Consumer Product Safety Commission to estimate the number of patients who visit emergency rooms annually because of adverse drug reactions.

Experts: Cough and cold medicines could put kids at risk

These findings should not come as a surprise – there have been multiple official statements regarding cough and cold management for children during the past decade.

In 1997, the American Academy of Pediatrics issued a policy statement advising that parents should be told that efficacy of the cough suppressants codeine and dextromethorphan in young children was unproven, and that there is a potential for adverse drug reactions.

In 2004, a systematic review done by the highly regarded Cochrane Collaboration, an international organization that reviews healthcare interventions, examined controlled clinical trials of over-the-counter cough and cold products. It found them no more effective than a placebo in reducing acute cough and other symptoms of upper respiratory tract infection (such as a cold).

Two years later, the American College of Chest Physicians advised health professionals to stop recommending cough suppressants and other over-the-counter cough medications for young children because of associated adverse effects and the possibility of death.

Small children require different doses of medications

No FDA-approved over-the-counter products have dosing recommendations for children less than 2 years old. Consumers are advised to consult their doctor for this age group.

Clinicians and health professionals commonly extrapolate a dose based on the patient's age or weight for children younger than 2. Such an extrapolation is based on assumption – which may not be true – that the effects of drugs are similar in adults and children. Children are not little adults, meaning that they may handle drugs in a different way.

What You Can Do

The common cold is a mild, self-limiting condition that will resolve in about seven days whether it is

continued on page 19

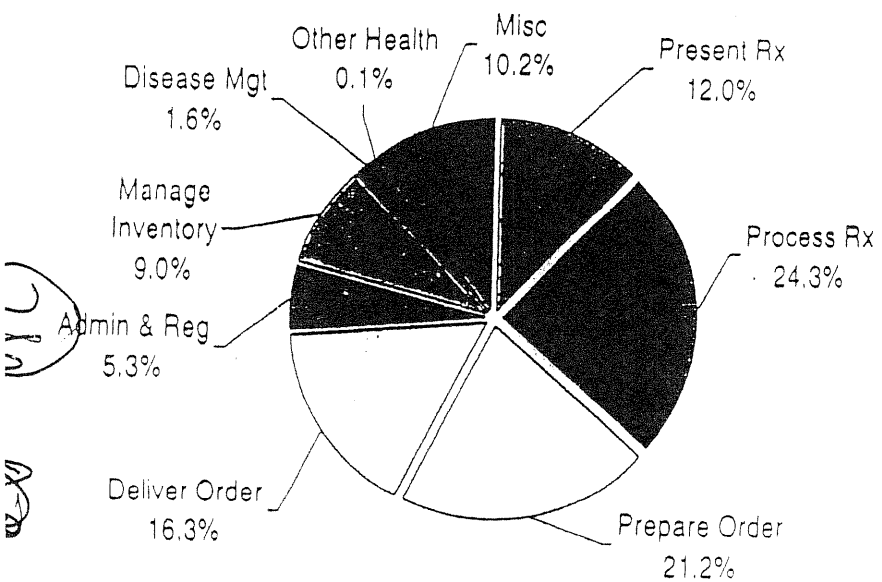
Executive Summary

(21)

rthur Andersen LLP was engaged to perform an independent study to identify the cost and effort associated with store-based harmacy related activities. Funding support was provided by the National Association of Chain Drug Stores (NACDS) ducation Foundation. The primary purpose of the study was to provide an assessment of the time and associated cost of erforming activities. Arthur Andersen LLP was also asked to provide observations and identify opportunities for performance nprovement at the stores.

summary, 73% of pharmacy personnel staff time was spent on processing orders and prescriptions, 9% on managing ventory, 5% on pharmacy administration and 13% on other miscellaneous activities. Pharmacists are spending over two-irds (68%) of their time on these activities.

Amount of Time Spent Per Pharmacy Process



Our analysis of the 36 discreet activities associated with processing orders and prescriptions suggests that pharmacists need only be involved in a few of these. We think that pharmacists need to be involved with reviewing and interpreting the prescription, assessing patients' drug therapy (including drug interactions), resolving clinical conflicts, contacting doctors concerning approvals or prescription clarification, and counseling patients about prescription. Pharmacists spend only 31% of their time on these activities, therefore a significant opportunity exists to transfer pharmacist time to ancillary personnel.

Helping In Ways You Never Imagined. ARTHUR ANDERSEN

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

NOTICE OF MEETING and AGENDA
Communication and Public Education Committee

Subcommittee on Medicare Drug Benefit Plans

Contact Person: Virginia Herold
(916) 574-7911

Time: 9:30- 12 noon
Date: November 30, 2006
Place: Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at (916) 574-7912, at least five working days before the meeting. Ms. Place can provide further information prior to the meeting and can be contacted at the telephone number and address set forth above. This notice is posted at www.pharmacy.ca.gov

Opportunities are provided for public comment on each agenda item.

MEETING AGENDA:

A.	Call to Order	9:30 a.m.
B.	Update of Medicare Part D Implementation – How Is It Going? Comments from Patient Advocates	
C.	Perspectives of the Centers for Medicare and Medicaid Services For 2007 and Future Program Activities -- Lucy Saldana	
D.	Policy and Implementation Issues Specific to California – Teri Miller, California Department of Health Services	
E.	Issues Involving Specialized Settings (e.g., Long-Term Care, Infusion Pharmacies)	
F.	Open Discussion on General Items of Interest for Pharmacies	
G.	Public Information Activities in Place or Needed	
H.	Adjournment	12 noon

(2)

pharmacists planning service, inc.
101 Lucas Valley Road, Suite 210 • San Rafael, California 94903
Tel: (415) 479-8628 • Fax: (415) 479-8608 • e-mail: ppsi@aol.com

California State Board of Pharmacy
Subcommittee on Medicare Drug Benefit Plans
November 30, 2006; 9:30 a.m. - 12 noon
Department of Consumer Affairs
1625 N. Market Boulevard
Sacramento, CA 95834

AMD
California Medicare Coalition (CMC)
Wednesday, December 13, 2006
10:00 am - Noon
Berkeley

Testimony of Fred S. Mayer, R.Ph., M.P.H.
President, Pharmacists Planning Service, Inc. (PPSI)

Meeting Agenda, Item No. G - Public Information Activities in Place or Needed

Thank you for inviting me to testify in today's Communication and Public Education Committee of the Subcommittee on Medicare Drug Benefit Plans.

I am Fred Mayer, R.Ph., M.P.H., President of Pharmacists Planning Service, Inc. (PPSI) a 501 C (3) nonprofit public health, consumer, pharmacy education organization. I have been a practicing pharmacist for over fifty years licensed in the State of California. I am also Past President of the California Public Health Association.

I would like to spend my time in responding to what needs to be done to fix the Medicare Part D system, as follows:

1. At the American Public Health Association (APHA) annual meeting held in Boston in November, 2006, PPSI put on a Medicare Part D Workshop (see pp 1)

2. One of the most glaring problems of the MMA program is the failure to have uniform standards for pharmacy practice (see pp 2).

3. Pharmacy practice for measuring quality and access to pharmacy services was adopted January 24, 1997 by CMS (see pp 3-4). Formulary development/quality.

4. Since the MMA has been privatized with no standards we see Medco, one of the largest PBMs and one of the big fours, paying a 155 million dollar fine to settle fraud/kick-back charges, illegal switching of drugs (see pp 5-6).

5. PPSI sees illegal activity of PBMs withholding information (see pp 7-10).

6. The number one problem that needs to be solved immediately is the lack of data and transparency which is not required under MMA. WE ARE TRYING TO FIX THIS LACK OF TRANSPARENCY WITH THE ENCLOSED FEDERAL REGISTRY TO SUPPORT CMS' EFFORTS TO MAKE PART D DATA AVAILABLE FOR RESEARCH. Please note

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7. Failure to have access to the information data and transparency issues results in fraud and abuse by the PBMs/PDPs/HMOs and managed care organizations.

8. Example: Dr. David Graham said five widely used drugs are called unsafe and should be off the market. (Dr. Graham spoke at the APHA annual meeting - see page 11).

9. These listed drugs are Accutane, Bextra (now off the market), Crestor, Meridia, and Serevent. Since most of the PBMs/PDPs, as you can see from the litigation, make their money from rebates/kick-backs and formularies, Crestor has now been put on many of the MMA formularies even though Dr. Graham said that it results in muscle-destroying side effects, Rhabdomylosis, and acute renal and kidney failure. One of top four, CCRx/PBM, now has Crestor as preferred brand. (pp0 12)

10. What is needed is evidence-based medicine similar to what they have in Oregon and also what we used to have under the old Medi-Cal drug formulary, a P & T or formulary committee with some oversight of CMS (see pp 13-14).

11. Finally, MMA must have a simple process method in order to get "medically needed" prescription drugs in a timely manner similar to the old Medi-Cal "treatment authorization request (TAR)" which is not available.

In conclusion, we need to do the following:

1. Adopt standards of practice for the pharmacy profession that has already been done.

2. Give CMS some congressional power for oversight which is presently not available.

3. Adopt some measures to get transparencies over the PBM/PDP industry.

4. Get evidence-based medicine (EBM) as soon as possible.

5. Get some "teeth" into the FDA so that they can control the industry.

6. Pharmacy has gone from 2 billion to 3 billion Rx's per year to now 4 billion in 2007. We need to fix the 30 day supply system so that all pharmacies are allowed to give 90 day maintenance drugs. This will reduce Rx's by 50% allowing pharmacists to consult and save consumers/patients' money on co-pays.

7. Finally, when all the above five fail, endorse the new Senate Bill SB 840 to get California citizens universal health care, single payer and healthcare for all.

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News XML

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Medco Health pays $155 million to settle fraud, kickback charges

LINDA A. JOHNSON
Associated Press

TRENTON, N.J. - Prescription-benefits manager Medco Health Solutions Inc. has agreed to pay $155 million in fines to settle fraud, kickback and other charges brought by federal prosecutors in Philadelphia in a whistleblower case dating to 1999.

The agreement, announced Monday by Pat Meehan, U.S. attorney for the Eastern District of Pennsylvania, involves multiple cases of alleged wrongdoing by Medco, the nation's No. 2 pharmacy benefit manager. The settlement comes nearly six months after the two sides announced an agreement in principle shortly before a trial was to begin.

"This settlement and others like it represent a sweeping change in the way pharmacy benefit managers do business," Meehan said in a statement, noting his office reached a $137 million settlement last year with Medco's biggest competitor, Nashville, Tenn.-based Caremark Rx Inc.

"Hidden financial agreements between PBMs and drug manufacturers and health plans, along with the bottom-line pressures of management, can influence which drugs patients receive, the price we all pay for drugs and whether pharmacists serve patients with their undivided professional judgment," Meehan said.

Franklin Lakes-based Medco said in a statement that there was no finding of wrongdoing by the company or any of its people, an agreement typical in government prosecutions of corporations.

"Even though we did nothing wrong, for our company and our clients it is the right decision to put these aged matters in the past," Medco said in a statement.

Among other charges, Medco was accused of paying health-insurance plans kickbacks to obtain their business and of soliciting kickbacks from drug manufacturers to favor their drugs over competitors' products, partly by illegally pressuring pharmacists and doctors

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- My Wedding

THE DAY IN PHOTOS

» Today's photos

» Photo Gallery

to switch prescriptions. Medco also was accused of destroying patient prescriptions when its mail-order pharmacies did not fill them as quickly as required by its insurance plan contracts.

Those issues were brought to light by three whistleblowers, Associate U.S. Attorney Jim Sheehan said in an interview. One of them was a government informant and the other two were pharmacists employed at Medco's Las Vegas pharmacy who told the government the operation was poorly run, with prescriptions with the wrong number of pills or other problems being shipped to customers anyway.

To settle those allegations, Medco will pay the government $137.5 million, Sheehan said. Medco also must set up a strict program to ensure it complies with all Medicare requirements and pharmacy practice requirements, with both an independent reviewer and the U.S. Attorney's Office reviewing its records annually for five years, he said.

Meanwhile, Medco will pay an additional $9.5 million to settle other civil charges in a case that Meehan's office expects to announce soon, Sheehan said.

The remaining $8 million will cover a third case, Sheehan said, involving a Medco program that helped its health plan clients get reimbursed by Medicare for diabetes testing supplies used by retired workers. Medco, which used a third-party contractor to run that program, reported problems with it to the U.S. Attorney's Office and ended the program, Sheehan said.

"What their contractor did was to create false documents to get payment from Medicare," Sheehan said.

Medco announced the tentative settlement on May 5, when it reported on its first-quarter profit. That quarter, Medco took a charge of $163 million before taxes, or 32 cents per share, to settle multiple federal legal cases.

The issues covered by the $163 million charge included inflating the drug prices government health programs paid to Medco, the company said at the time.

Medco handles prescription benefits for about 58 million Americans, either by processing electronic claims from retail pharmacies or by shipping medications directly from its dozen mail-order pharmacies around the country.

In trading on the New York Stock Exchange Monday, Medco shares rose 12 cents to $57.60.

—

On the Net: http://www.medco.com

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Who Will Choose Your Medications?

David B. Nash, MD, MBA

[redacted]

Surprise, Again — MD's where have you been? Fred

A battle now brewing in Washington, D.C., over the new Medicare drug benefit could seriously limit the choice of medications that will be available to physicians and patients. If the approach supported by health insurance plans is adopted, it will open the door for excessive new restrictions on access to medications.

The struggle is centered on guidelines now under development that provide a "model of the types (or "categories and classes") of agents that should be available to senior citizens and people with disabilities under the new Medicare prescription drug benefit.

If the guidelines list too few classes of drugs, insurers will gain more power to limit the number of medications available for each disease or condition. The outcome could determine whether the elderly and the disabled will have access to the medications they need.

Good health policy and medical practice require protecting physicians' ability to choose from among a broad range of pharmaceutical agents. However, the initial draft of the Medicare guidelines, written by a private organization called the U.S. Pharmacopeia (USP), does not provide this protection.

The USP model, if followed by insurance plans, would leave Medicare patients with many common diseases and conditions more vulnerable to excessive restrictions on their access to medications. Treatment of high blood pressure, which affects more than 50% of all Medicare patients, is just one example, with angiotensin-converting enzyme (ACE)–inhibitors being one of the most common types of drugs used for this purpose. Currently, 10 ACE-inhibitors are available to physicians. Because of differences in these drugs and differences in patients' needs, physicians rely on a range of ACE-inhibitors in caring for patients.

The same is true for selective serotonin reuptake inhibitors (SSRIs). Research shows that although these medications *on average* are equally effective, they are not equally effective for individual patients. Studies also have found that between 20% and 40% of patients do not respond to a given SSRI and that patients who do not do well with an initial SSRI often are successfully treated with an alternative drug in this class.

In light of these important differences, patients covered under Medicare need safeguards that will ensure that their health care providers can choose from among a range of medications within each class (such as the ACE-inhibitors and SSRIs). Unfortunately, the guidelines drafted by USP lack this basic protection.

In an era of increased health spending, cost containment is important; however, it should not come at the expense of quality patient care. The USP guidelines should be fixed, and they should be fixed now. If the organization truly wants to help Medicare patients, it should go back to the drawing board and devise guidelines that safeguard the ability of a physician to choose the medicine that is best for the individual patient.

As usual, I am interested in your views. You can reach me at david.nash@jefferson.edu.

David B. Nash

Walter L. Way, M.D.
Box 191
Ross, CA 94957

(415) 461-4166 Fax (415) 925-1563
e-mail wayr@earthlink.net

Kimberly Belshe
Director, California Dept. HSS
711 "P" Street
Sacramento CA, 95834

RE: 90 day drug supply, availability in community pharmacies

Dear Kim,

May I ask that you or appropriate people in your department address a serious problem with regard consumer drug availability. In order to obtain a 90 day supply of medication the supply must be obtained from a pharmacy provider ie Precison Rx designated by the PBM supervising the Part D plan used by the patient. After ordering the drug it is supposedly returned by USMail in 5-7 business days. The enclosed letter details the difficulties Betty faced in attempting to get her glaucoma Rx which has been sent to the Pharmacy Board president.

In addition, I include a copy of testimony given on 11/30/06 to the CaBd of Pharmacy, Subcommittee on Medicare Drug Benefits Plans by Fred S. Mayer,RPh.,M.P.H.. Please note highlighted item #6 of his remarks.

I think you can understand the difficulties facing Medicare patients attempting to navigate the many obstacles that PBMs have placed in the path of the poor patient. This is really unfair to all patients but particularly the elderly. Any help you can provide would be welcome!

All the best and we hope we will see you over the holidays.

Sincerely,

Walter L. Way, MD
Professor Emeritus, Anesthesia/Molecular Pharmacology
University of California, San Francisco

Walter L. Way, M.D.
Box 191
Ross, CA 94957

(415) 461-4166 Fax (415) 925-1563
E-mail ways@earthlink.net

Bill Powers, President
California Board of Pharmacy
1625 N. Market Boulevard N219
Sacramento, CA 95834

RE: Community Pharmacies--Inability to fill 90 day Rxs

Dear President Powers,

This letter concerns one of the many problems with Medicare Drug Benefits including Part D. My wife is a Medicare participant with Blue Cross Rx as our Part D provider. She suffers from preglaucomatous optic hypertension, which has been successfully treated with Travatan. We usually get a 90-day supply of her drugs from Precision Rx, which is the drug provider chosen by the PBM, Wellpoint.

In mid-November we submitted her prescription to Precision Rx and received word that it had been mailed on 11/21. When it did not arrive by 12/1 we obtained another Rx and presented it to our local pharmacy. Wellpoint denied them authorization because the original had been filled and sent out by Precision. This caused us great distress given her optic pressure problem and the possibility of stroke and/or blindness. After 12 phone calls to various Wellpoint personnel we found that there *was* a means to take care of patients and we finally purchased Travatan on Saturday at 5:30pm from our local pharmacy!

Our question is "Why can't community pharmacies be allowed to provide their patients with 90-day supplies?" Two benefits could be patient convenience (obtaining fairly priced medication without depending on USPS), and reduced cost because of one co-pay instead of three.

We hope that you and the Board can pursue this unfair practice.

Sincerely yours:

Walter L. Way, RPh, MD
Professor Emeritus, Anesthesia/Molecular Pharmacology
University of California, San Francisco

kickbacks.

I plead with the Federal Trade Commission to vigorously continue to seek to identify and challenge any merger or acquisition that the Agency has a reason to believe violates the antitrust laws. PPSI in the above letter documents thirteen of these transactions that may harm competition and consumers.

Sincerely,

Fred S. Mayer, R.Ph., M.P.H.
President, PPSI

cc: Jon Platt
Federal Trade Commission
Northeast Region
One Bowling Green, Suite 318
New York, NY 10004

FDA tells ADHD drugmakers to expand health warnings

By Jonathan D. Rockoff
BALTIMORE SUN

WASHINGTON — The makers of Ritalin, Adderall, Strattera and other drugs treating attention-deficit hyperactivity disorder were advised by the government Wednesday to give patients and their parents an additional warning that those medicines can cause serious psychiatric and heart problems, including sudden death.

Patients would receive two-page "medication guides" upon picking up a prescription. The guides warn about possible side effects and urge patients to notify doctors immediately after any sign of heart or psychiatric problems, such as chest pain, shortness of breath, fainting or hallucinations.

Dr. Tom Laughren, director of psychiatry products at the Food and Drug Administration, emphasized that the move was precautionary and should not frighten patients away from taking the drugs, which he said were safe. He said he expected the manufacturers of the 15 drugs to comply with the request within 30 days.

An estimated 3.3 million children and 1.5 million adults take ADHD drugs, whose sales exceed $3.5 billion a year. Their use has been dogged by concerns about overuse in children and side effects, prompted by scattered reports of children dying suddenly. Some of the children were later determined to have had heart defects.

The latest action expands upon a move the government made last year, when the FDA asked manufacturers to revise ADHD drug labels to alert prospective patients with heart problems and warn of hallucinations in 1 child out of 1,000.

Dr. Richard L. Gorman, a pediatrician who served on an FDA advisory panel that recommended the warnings about ADHD drugs, said the medication guides "are in line with" what the committee recommended. Gorman said parents must pay close attention to their children's reactions to the drugs because children may take them for years.

Laughren said it took until now to work out the wording of the medication guides, which are more simply worded than drug labels. Companies may tweak the language that the FDA proposed, he added.

More than 2,500 children who took ADHD drugs went to emergency rooms in 2004, and about a quarter of them had serious heart or blood pressure problems, the Centers for Disease Control reported last year. Twenty-five deaths, 19 involving children, linked to the drugs were reported to the FDA from 1999 to 2003. Fifty-four strokes, heart attacks and other heart issues were also reported; some of those patients had prior heart conditions.

The proposed guides warn that the drugs have been linked to stroke and heart attacks in adults and sudden death in patients with heart problems or defects. The guides say some children and teenagers said they had heard voices, grown suspicious or become manic after taking the drugs.

Patients are urged to give doctors a full history of cardiovascular or mental problems and tell physicians if they take antidepressants, seizure medicines or blood thinners, the FDA advises. It says ADHD drugs shouldn't be taken by patients with heart disease, blood pressure problems, hyperthyroidism or glaucoma.

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Useful drug information: 20 years and still waiting

Are patients getting sound written drug information with their new prescriptions? This issue has been at the center of a contentious debate for more than 20 years. The divisions have been along ideological lines—with pharmacists and their associations favoring a "marketplace for information" and consumers preferring a government-regulated program with quality standards and oversight.

The issue dates back to 1979, when the Food & Drug Administration proposed the first plan. It was killed in the early days of the Reagan Administration. In 1982, the National Council on Patient Information & Education (NCPIE) was formed, pledging to meet patients' information needs.

In 1995, the FDA proposed the Medication Guide rule. The same ideological forces that divided the FDA's 1979 plan greeted this proposal. A compromise was struck over the Medication Guide rule with the passage of Public Law 104-180 in 1996. This law called for the FDA to assess the effectiveness of current private-sector approaches to providing patients with drug information. If 75% of patients receiving new Rxs did not receive useful written information by the year 2000, the Department of Health & Human Services would be required to explore other initiatives. The HHS Secretary accepted the "Action Plan," as it was known, on Jan. 13, 1997. The Action Plan stated that drug leaflets to patients should be accurate, unbiased, sufficiently comprehensive, understandable, timely, and useful.

Next, the FDA granted a contract to the University of Wisconsin School of Pharmacy to conduct a national assessment of patient information leaflets. In June 2002, the FDA released the results of this assessment, which covered about 1,300 leaflets distributed nationally by pharmacists for atenolol, atorvastatin, glyburide, and nitroglycerin. The survey found that while 89% of patients received some written information, the information was only about 50% useful.

To Public Citizen, the concept that drug information can be 50% useful is unfathomable. Drug information that contains only half of what it should is misleading, and misleading drug information is potentially dangerous.

Based on the survey results, FDA concluded that progress has been made in meeting the goals set under the law. The agency said it would continue to work with private sector partners to improve the usefulness of patient information and meet the goal for the year 2006, which calls for 95% of patients obtaining new prescriptions to receive useful written drug information at the time of dispensing.

by Larry Sasich, Pharm.D.

Following the FDA's decision to delay action until 2006, Public Citizen's Health Research Group filed suit against the agency this past February, challenging the FDA's failure to seek public comment as required by the law. Negotiations began almost immediately, and the suit was settled in April. In the settlement, the FDA agreed to hold a public meeting this month and to open a docket to seek public comment. It is expected that some at this meeting will raise the issue of pharmacist counseling and oral information provided by health professionals.

Consumer groups are strongly supportive of verbal interactions between healthcare professionals and consumers, but given the limited amount of drug information that can be communicated to and retained by a consumer in this type of interaction, we continue to believe that FDA-approved written information provides patients with the best opportunity to avoid preventable adverse drug reactions. An August 1997 Office of Inspector General report found that enforcement of patient counseling laws by state pharmacy boards has been minimal, underscoring the need for mandatory distribution of FDA-approved written drug information.

Several professional trade organizations, including some representing pharmacy, have consistently supported the distribution of high-quality drug information for consumers. However, these same organizations also oppose FDA oversight of quality guidelines such as those contained in the Action Plan. Claiming support while opposing regulatory oversight is disingenuous and does nothing for the image of pharmacy as a health profession. The results of the University of Wisconsin survey clearly show the poor quality of drug information that consumers can expect without active FDA oversight of quality guidelines.

With the settlement of the Public Citizen lawsuit, patient information leaflets will once again come up for public debate. Pharmacy could cultivate smarter patients by remembering that voluntary programs have failed for 20 years and by supporting the only viable alternative available—an FDA-regulated program.

THE AUTHOR is a research analyst for Health Research Group, a division of the consumer advocacy organization Public Citizen.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 26 2005

NOTE // OVER 5 years to do!!

Frederick S. Mayer, R. Ph., M.P.H.
President/CEO
Pharmacists Planning Services, Inc.
101 Lucas Valley Road, Suite 210
San Rafael, CA 94903

Re: Docket No. 2000P-1671/CP1

Dear Mr. Mayer:

This letter responds to the citizen petition submitted by Pharmacists Planning Services, Inc., requesting that the Food and Drug Administration (FDA) issue a patient medication guide (MedGuide) for distribution with all prescription non-steroidal anti-inflammatory drugs (NSAIDs), including the so-called "COX-2 selective" drugs, to provide patients appropriate warning and risk information relating to gastrointestinal (GI) bleeding associated with the use of these drugs. For the reasons described below, your petition is granted.

On April 7, 2005, FDA issued a Public Health Advisory (PHA) in which it announced several actions relating to both COX-2 selective and non-selective NSAIDs, including plans to issue a MedGuide for patients addressing the cardiovascular and GI risks associated with the use of prescription drugs in this class. The MedGuide will inform patients of the need to discuss with their doctor the risks and benefits of using prescription NSAIDs, and the importance of using the lowest effective dose for the shortest duration possible if treatment with an NSAID is warranted for an individual patient.

We have attached the PHA and related documents issued by FDA on April 7, and our memorandum entitled "Analysis and recommendations for Agency action regarding non-steroidal anti-inflammatory drugs and cardiovascular risk." These documents detail the scientific and regulatory findings upon which FDA based these actions.

Accordingly, your petition is granted. Thank you for your continuing interest in promoting public awareness of safe use of medications.

Sincerely,

NOTE!! [signature]

Steven K. Galson, M.D., M.P.H.
Acting Director
Center for Drug Evaluation and Research

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Attachments

Get emergency help right away if you have any of the following symptoms:

- shortness of breath or trouble breathing
- chest pain
- weakness in one part or side of your body
- slurred speech
- swelling of the face or throat

Stop your NSAID medicine and call your healthcare provider right away if you have any of the following symptoms:

- nausea
- more tired or weaker than usual
- itching
- your skin or eyes look yellow
- stomach pain
- flu-like symptoms
- vomit blood
- there is blood in your bowel movement or it is black and sticky like tar
- skin rash or blisters with fever
- unusual weight gain
- swelling of the arms and legs, hands and feet

These are not all the side effects with NSAID medicines. Talk to your healthcare provider or pharmacist for more information about NSAID medicines.

Other information about Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

Aspirin is an NSAID medicine but it does not increase the chance of a heart attack. Aspirin can cause bleeding in the brain, stomach, and intestines. Aspirin can also cause ulcers in the stomach and intestines. Some of these NSAID medicines are sold in lower doses without a prescription (over –the –counter). Talk to your healthcare provider before using over–the–counter NSAIDs for more than 10 days.

NSAID medicines that need a prescription

Generic Name	Tradename
Celecoxib	Celebrex
Diclofenac	Cataflam, Voltaren, Arthrotec (combined with misoprostol)
Diflunisal	Dolobid
Etodolac	Lodine, Lodine XL
Fenoprofen	Nalfon, Nalfon 200
Flurbiprofen	Ansaid
Ibuprofen	Motrin, Tab-Profen, Vicoprofen (combined with hydrocodone), Combunox (combined with oxycodone)
Indomethacin	Indocin, Indocin SR, Indo-Lemmon, Indomethagan
Ketoprofen	Oruvail
Ketorolac	Toradol
Mefenamic Acid	Ponstel
Meloxicam	Mobic
Nabumetone	Relafen
Naproxen	Naprosyn, Anaprox, Anaprox DS, EC-Naprosyn, Naprelan, PREVACID NapraPAC (copackaged with lansoprazole)
Oxaprozin	Daypro
Piroxicam	Feldene
Sulindac	Clinoril
Tolmetin	Tolectin, Tolectin DS, Tolectin 600

This Medication Guide has been approved by the U.S. Food and Drug Administration.

(See the end of this Medication Guide for a list of prescription NSAID medicines.)

What is the most important information I should know about medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)?

NSAID medicines may increase the chance of a heart attack or stroke that can lead to death. This chance increases:

- with longer use of NSAID medicines
- in people who have heart disease

NSAID medicines should never be used right before or after a heart surgery called a "coronary artery bypass graft (CABG)."

NSAID medicines can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Ulcers and bleeding:

- can happen without warning symptoms
- may cause death

The chance of a person getting an ulcer or bleeding increases with:

- taking medicines called "corticosteroids" and "anticoagulants"
- longer use
- smoking
- drinking alcohol
- older age
- having poor health

NSAID medicines should only be used:

- exactly as prescribed
- at the lowest dose possible for your treatment
- for the shortest time needed

What are Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)?

NSAID medicines are used to treat pain and redness, swelling, and heat (inflammation) from medical conditions such as:

- different types of arthritis
- menstrual cramps and other types of short-term pain

Who should not take a Non-Steroidal Anti-Inflammatory Drug (NSAID)?

Do not take an NSAID medicine:

- if you had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAID medicine
- for pain right before or after heart bypass surgery

Tell your healthcare provider:

- about all of your medical conditions.
- about all of the medicines you take. NSAIDs and some other medicines can interact with each other and cause serious side effects. **Keep a list of your medicines to show to your healthcare provider and pharmacist.**
- if you are pregnant. **NSAID medicines should not be used by pregnant women late in their pregnancy.**
- if you are breastfeeding. **Talk to your doctor.**

What are the possible side effects of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)?

Serious side effects include:

- heart attack
- stroke
- high blood pressure
- heart failure from body swelling (fluid retention)
- kidney problems including kidney failure
- bleeding and ulcers in the stomach and intestine
- low red blood cells (anemia)
- life-threatening skin reactions
- life-threatening allergic reactions
- liver problems including liver failure
- asthma attacks in people who have asthma

Other side effects include:

- stomach pain
- constipation
- diarrhea
- gas
- heartburn
- nausea
- vomiting
- dizziness

MEDICATION GUIDE

COUMADIN® (COU-ma-din) Tablets
(Warfarin Sodium Tablets, USP) Crystalline

Read this Medication Guide before you start taking COUMADIN (Warfarin Sodium) and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. You and your healthcare provider should talk about COUMADIN when you start taking it and at regular checkups.

What is the most important information I should know about COUMADIN?

Take your COUMADIN exactly as prescribed to lower the chance of blood clots forming in your body. (See **"What is COUMADIN?"**).

COUMADIN is very important for your health, but it can cause serious and life-threatening bleeding problems. To benefit from COUMADIN and also lower your chance for bleeding problems, you must:

- **Get your regular blood test to check for your response to COUMADIN.** This blood test is called a PT/INR test. The PT/INR test checks to see how fast your blood clots. Your healthcare provider will decide what PT/INR numbers are best for you. Your dose of COUMADIN will be adjusted to keep your PT/INR in a target range for you.
- **Call your healthcare provider right away if you get any of the following signs or symptoms of bleeding problems:**
  - pain, swelling or discomfort
  - headaches, dizziness, or weakness
  - unusual bruising (bruises that develop without known cause or grow in size)
  - nose bleeds
  - bleeding gums
  - bleeding from cuts takes a long time to stop
  - menstrual bleeding or vaginal bleeding that is heavier than normal
  - pink or brown urine
  - red or black stools
  - coughing up blood
  - vomiting blood or material that looks like coffee grounds

Many other medicines, including prescription and non-prescription medicines, vitamins and herbal supplements can interact with COUMADIN and:

- **affect the dose you need, or**
- **increase COUMADIN side effects.**

Tell your healthcare provider about all the medicines you take. Do not stop medicines or take anything new unless you have talked to your healthcare provider. Keep a list of your medicines with you at all times to show your healthcare provider and pharmacist.

Do not take other medicines that contain warfarin. **Warfarin is the active ingredient in COUMADIN.**

Some foods can interact with COUMADIN:

- **Eat a normal, balanced diet.** Talk to your doctor before you make any diet changes. **Do not eat large amounts of leafy green vegetables.** Leafy green vegetables contain Vitamin K. Certain vegetable oils also contain large amounts of Vitamin K. Too much Vitamin K can lower the effect of COUMADIN.
- **Avoid drinking cranberry juice or eating cranberry products.**
- **Avoid drinking alcohol.**
- **Always tell all of your healthcare providers that you take COUMADIN.**
- **Wear or carry information that you take COUMADIN.**

What is COUMADIN?

COUMADIN is an anticoagulant medicine. It is used to lower the chance of blood clots forming in your body. Blood clots can cause a stroke, heart attack, or other serious conditions such as blood clots in the legs or lungs.

Who should not take COUMADIN?

Do not take COUMADIN if:

- **your chance of having bleeding problems is higher than the possible benefit of treatment.** Your healthcare provider will decide if COUMADIN is right for you. Talk to your healthcare provider about all of your health conditions.
- **you are pregnant or plan to become pregnant.** COUMADIN can cause death or birth defects to an unborn baby. Use effective birth control if you can get pregnant.
- **you are allergic to warfarin or to anything else in COUMADIN.**

What should I tell my healthcare provider before starting COUMADIN?

Tell your healthcare provider about all of your health conditions, including if you:

- **have bleeding problems**
- **fall often**
- **have liver or kidney problems**
- **have high blood pressure**
- **have a heart problem called congestive heart failure**
- **have diabetes**
- **drink alcohol or have problems with alcohol abuse.** Alcohol can affect your COUMADIN dose and should be avoided.
- **are pregnant or planning to become pregnant.** See **"Who should not take COUMADIN?"**
- **are breastfeeding.** COUMADIN may increase bleeding in your baby. Talk to your doctor about the best way to feed your baby. If you choose to breastfeed while taking COUMADIN, both you and your baby should be

· healthcare provider about all the medicines you
· including prescription and non-prescription medi-
ıes, vitamins, and herbal supplements. See **"What is**
: **most important information I should know about**
UMADIN® (Warfarin Sodium)?"

w should I take COUMADIN?

Take COUMADIN exactly as prescribed. Your health-
:are provider will adjust your dose from time to time
depending on your response to COUMADIN.

/ou must have regular blood tests and visits with your
ıealthcare provider to monitor your condition.

Take COUMADIN at the same time every day. You can
ake COUMADIN either with food or on an empty stomach.

f you miss a dose of COUMADIN, call your healthcare
›rovider. Take the dose as soon as possible on the
;ame day. Do not take a double dose of COUMADIN the
ıext day to make up for a missed dose.

:all your healthcare provider right away if you take too
nuch COUMADIN.

:all your healthcare provider if you are sick with diar-
hea, an infection, or have a fever.

'ell your healthcare provider about any planned surger-
es, medical or dental procedures. Your COUMADIN may
ıave to be stopped for a short time or you may need
our dose adjusted.

:all your healthcare provider right away if you fall or
ıjure yourself, especially if you hit your head. Your
ealthcare provider may need to check you.

ıat should I avoid while taking COUMADIN?

)o not start, stop, or change any medicine without talk-
ıg with your healthcare provider.

)o not make changes in your diet, such as eating large
mounts of green, leafy vegetables.

)o not change your weight by dieting, without first check-
ıg with your healthcare provider.

void drinking alcohol.

)o not do any activity or sport that may cause a serious
ıjury.

at are the possible side effects of COUMADIN?

OUMADIN is very important for your health, but it can
ause serious and life-threatening bleeding problems.
ee **"What is the most important information I should**
now about COUMADIN?"

erious side effects of COUMADIN also include:

death of skin tissue (skin necrosis or gangrene). This
can happen soon after starting COUMADIN. It happens
because blood clots form and block blood flow to an
area of your body. Call your healthcare provider right
away if you have pain, color, or temperature change to
any area of your body. You may need medical care
right away to prevent death or loss (amputation) of
your affected body part.

"purple toes syndrome." Call your healthcare provider
right away if you have pain in your toes and they look
purple in color or dark in color.

Other side effects with COUMADIN include allergic reactions, liver problems, low blood pressure, swelling, low red blood cells, paleness, fever, and rash. Call your healthcare provider if you have any side effect that bothers you.

These are not all of the side effects of COUMADIN. For more information, ask your healthcare provider or pharmacist.

How should I store COUMADIN?

- Store COUMADIN at room temperature between 59° and 86° F. Protect from light.
- **Keep COUMADIN and all medicines out of the reach of children.**

General Information about COUMADIN

Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide. Do not use COUMADIN for a condition for which it was not prescribed. Do not give COUMADIN to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about COUMADIN. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about COUMADIN that was written for healthcare professionals.

Botanical (Herbal) Medicines

Caution should be exercised when botanical medicines (botanicals) are taken concomitantly with COUMADIN. Few adequate, well-controlled studies exist evaluating the potential for metabolic and/or pharmacologic interactions between botanicals and COUMADIN. Due to a lack of manufacturing standardization with botanical medicinal preparations, the amount of active ingredients may vary. This could further confound the ability to assess potential interactions and effects on anticoagulation. It is good practice to monitor the patient's response with additional PT/INR determinations when initiating or discontinuing botanicals.

Specific botanicals reported to affect COUMADIN therapy include the following:

- Bromelains, danshen, dong quai *(Angelica sinensis)*, garlic, Ginkgo biloba, ginseng, and cranberry products are associated most often with an INCREASE in the effects of COUMADIN.
- Coenzyme Q_{10} (ubidecarenone) and St. John's wort are associated most often with a DECREASE in the effects of COUMADIN.

Some botanicals may cause bleeding events when taken alone (e.g., garlic and Ginkgo biloba) and may have anticoagulant, antiplatelet, and/or fibrinolytic properties. These effects would be expected to be additive to the anticoagulant effects of COUMADIN. Conversely, other botanicals may have coagulant properties when taken alone or may decrease the effects of COUMADIN.

Some botanicals that may affect coagulation are listed below for reference; however, this list should not be considered all-inclusive. Many botanicals have several common names and scientific names. The most widely recognized common botanical names are listed.

Botanicals that contain coumarins with potential anticoagulant effects:		
Alfalfa	Celery	Parsley
Angelica (Dong Quai)	Chamomile (German and Roman)	Passion Flower
Aniseed	Dandelion[3]	Prickly Ash (Northern)
Arnica	Fenugreek	Quassia
Asa Foetida	Horse Chestnut	Red Clover
Bogbean[1]	Horseradish	Sweet Clover
Boldo	Licorice[2]	Sweet Woodruff
Buchu	Meadowsweet[1]	Tonka Beans
Capsicum[2]	Nettle	Wild Carrot
Cassia[3]		Wild Lettuce
Miscellaneous botanicals with anticoagulant properties:		
Bladder Wrack *(Fucus)*	Pau d'arco	
Botanicals that contain salicylate and/or have antiplatelet properties:		
Agrimony[4]	Dandelion[3]	Meadowsweet[1]
Aloe Gel	Feverfew	Onion[5]
Aspen	Garlic[5]	Policosanol
Black Cohosh	German Sarsaparilla	Poplar
Black Haw	Ginger	Senega
Bogbean[1]	Ginkgo Biloba	Tamarind
Cassia[3]	Ginseng *(Panax)*[5]	Willow
Clove	Licorice[3]	Wintergreen
Botanicals with fibrinolytic properties:		
Bromelains	Garlic[5]	Inositol Nicotinate
Capsicum[2]	Ginseng *(Panax)*[5]	Onion[5]
Botanicals with coagulant properties:		
Agrimony[4]	Mistletoe	
Goldenseal	Yarrow	

[1]Contains coumarins and salicylate
[2]Contains coumarins and has fibrinolytic properties
[3]Contains coumarins and has antiplatelet properties
[4]Contains salicylate and has coagulant properties
[5]Has antiplatelet and fibrinolytic properties

T1-DD0048 10/06

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 20, 2006

Frederick S. Mayer, R.Ph., M.P.H.
Pharmacists Planning Service, Inc.
101 Lucas Valley Road
Suite 384
San Rafael, California 94903

Dear Dr. Mayer:

Your petition requesting the Food and Drug Administration to regulate labeling and packaging of Acetaminophen/APAP containing products was received by this office on 10/19/2006. It was assigned docket number 2006P-0423/CP 1 and it was filed on 10/19/2006. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie Butler, Director
Division of Dockets Management
Office of Management Programs
Office of Management

SEND ALL RESPONSES TO ... THANKS - FRED MAYER

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DEPARTMENT OF
HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

pharmacists planning service, inc.
101 Lucas Valley Road, Suite 210 • San Rafael, California 94903
Tel: (415) 479-8628 • Fax: (415) 479-8608 • e-mail: ppsi@aol.com

October 23, 2006

Documents Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

The undersigned submits this Petition under Section 21 CFR 10.20 and 21 CFR 10.30 and other pertinent sections of the Federal Food and Cosmetic Act or any other statutory provision which authority has been delegated of the Commissioner of Food and Drug to request the FDA Commissioner to regulate labeling and packaging of Acetaminophen/APAP containing products.

I strongly request that you immediately consider this petition which has been signed by twenty-three (23) physicians along with pharmacists in the interest of public health and safety.

Sincerely,

Frederick S. Mayer, R.Ph., M.P.H.
President, Pharmacists Planning Service, Inc. (PPSI)
101 Lucas Valley Road, Suite 384
San Rafael, California 94903
Telephone: 415 479-8628; Fax: 415 479-8608
Email: ppsi@aol.com; Website: www.ppsinc.org

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Dockets Management Branch,
Food and Drug Administration,
Room 1061,
5630 Fishers Lane,
Rockville, MD 20852

October 11, 2006

The undersigned submit this Petition under Section 21 CFR 10.20 and 21 CFR 10.30 and other pertinent sections of the Federal Food, Drug and Cosmetic Act or any other statutory provision which authority has been delegated of the Commissioner of Food and Drug to request the FDA Commissioner to regulate labeling and packaging of Acetaminophen/APAP containing products.

ACTIONS REQUESTED:

1. Mandate all non-aspirin containing OTC medicines with Acetaminophen/APAP to be clearly labeled "Contains Acetaminophen. Do not take with any other Acetaminophen/APAP"
2. Regulate maximal Acetaminophen/APAP dosage/number of pills. We suggest 500 mg. tablets to be no more than 32 or 16 in a pack, that is 16 or 8 gms. and that the pack be mandated to be in blister packs
3. Mandate the association of Acetaminophen/APAP containing tablets with an FDA-approved MedGuide detailing the recommended dosages and possible adverse drug events of these products, including increased risks with chronic alcohol consumption.

Multiple FDA-issued letters and Board of Pharmacy letters, January-February, 2003, FDA Consumer Magazine articles both Dr. Stephen Galson, M.D., MPH of the FDA, have addressed the above issues without substantive regulatory action or a decrease in APAP toxicity cases; in fact, liver toxicity from APAP is now the number one cause of acute liver failure in the United States (see below).

STATEMENTS OF SCIENTIFIC BASIS FOR PETITION:

1. Acetaminophen/Tylenol products are marketed for pain relief, to reduce fevers, headaches, toothaches, sore throats, migraines, neuralgia, menstruation pain, backaches, aches and pains from cold and flu and many other medically indicated conditions.

2. Most consumer/patients do not know that Tylenol is Acetaminophen (APAP).

3. Most consumer/patients do not know that Acetaminophen (APAP) is present in > 100 preparations with different names. 38% patients with APAP-induced liver failure took two different preparations containing APAP (1)

4. Most consumer/patients are not aware that there are a number of scientific reports stating that chronic alcohol use is associated with more severe outcome. It is usually stated that if a patients consumes three or more alcohol beverages daily, he/she should take no more than 2 gm. of APAP daily vs. the official maximum recommended dose of 4 g. Acute liver failure has been well documented in these cases (1, 2)

5. The minimum APAP intake associated with unintentional toxicity was 1 gram/day, well below the maximum recommended dose (1)

6. The number one generic prescription drug being dispensed in the USA today is Vicodin and its generic equivalent Hydrocodone Bitartrate with Acetaminophen, 5 mg-500 mg with over 100 million prescriptions. Vicodin as well as other similar narcotic-containing combinations contain Acetaminophen (APAP) anywhere from 325 mg to 750 mg. A recent study suggested that 62% of unintentional APAP overdoses leading to acute liver failure were using a narcotic-containing preparation, often for more than 30 days suggesting addiction to the narcotic with gradual increasing dosage (4).

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7. Acute liver failure (ALF) cases caused by Acetaminophen/Tylenol rose from 28% in 1998 to 51% in 2004 and was 49% in 2005. This research project was conducted by the US Acute Liver Failure Study Group (ALFSG). Acetaminophen hepatotoxicity far exceeds other causes of acute liver failure in the United States (1, 5).

8. The ALFSG also found that 178 or 65% of 275 patients identified as having APAP-induced liver toxicity survive. 74 patients, or 27%, died without a liver transplant; 23 patients, or 8%, underwent a liver transplant operation (5).

9. Recently the administration of therapeutic dosages of APAP to normal volunteers resulted in their tripling their baseline transaminases in 65% of the cases. About 40% of normal individuals developed transaminases > three times the upper limit of normal (6).

References:

1. Blendis L. Gastroenterology 2006;131:963-4.
2. Draganov P et al. Postgrad Med 2000;107(1):189-95
3. Drug Topics Magazine online, March 20, 2006.
4. Drug Topics Magazine, August 7, 2006, pp. 63-65
5. Larson et al. Hepatology 2005;42:1364-1372.
6. Watkins P et al. JAMA 2006;296:87-93.

There is no environmental impact associated with this Citizen's Petition and we wish to be excluded under 21 CFR Sec. 25.24.

The undersigned certify, that, to the best knowledge and belief of the undersigned this Petition includes all information and view on which the Petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the Petition (21 CFR Sec. 10.30b).

Signature

Name of Petitioners:

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President, Pharmacists Planning Service, Inc. (PPSI)
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Natalie Bzowej, M.D.
Department of Transplantation

(89) (08)

PPSI to FDA: Regulate acetaminophen labeling

Sandra Levy

Pharmacists Planning Service Inc. (PPSI) has submitted a citizen's petition to the Food & Drug Administration to regulate the labeling and packaging of acetaminophen/APAP-containing products so that the label states, "Contains acetaminophen. Do not take with any other acetaminophen/ APAP." PPSI is also asking that no more than 50 tablets be sold in a bottle and that the FDA mandate a MedGuide.

"Most people don't know Tylenol is acetaminophen, and they certainly don't know that APAP (the abbreviation for acetaminophen) is in Vicodin and other products," explained Fred Mayer, R.Ph., president of PPSI. Pointing out that in England acetaminophen can only be sold behind the pharmacy counter, Mayer said the maximum the pharmacist can sell is up to 32 tablets. "We're asking for up to 50 as the maximum quantity that can be sold."

Matthew Seamon

Maurizio Bonacini, M.D., transplant hepatologist at the California Pacific Medical Center, San Francisco, who signed the petition, told *Drug Topics*, "There are data showing that acetaminophen is the No. 1 cause of liver failure."

Bonacini referred to a study published in the July 5 issue of the *Journal of the American Medical Association (JAMA)* that showed an association between the dosage of 4 gm a day of acetaminophen and elevated alanine aminotransferase (ALT) levels.

What does the pharmacy community think about this petition? Matthew Seamon, Pharm.D., assistant professor at Nova Southeastern University College of Pharmacy, Ft. Lauderdale, Fla., thinks consumers should be made more aware of the risks of taking cough and cold medications at the same time as pain medications that contain acetaminophen.

Janet Engle

Seamon said he would not like to see pregnant women's access to acetaminophen limited, because they might take a nonsteroidal anti-inflammatory drug (NSAID) instead. "That is probably less safe for a pregnant woman," he asserted.

Janet Engle, Pharm.D., associate dean for academic affairs and clinical professor of pharmacy practice at the University of Illinois at Chicago College of Pharmacy, pointed out that acetaminophen dosing information for children under the age of two is needed. Engle said parents don't always call their physician to find out the correct dose to give their children. "They just guess, and that could lead to overdosing or underdosing," she contended.

Rick Dart

Paul Lofholm, Pharm.D., clinical professor of pharmacy at University of California School of Pharmacy, warned that recent data suggest that women who took Tylenol on a chronic basis had a higher incidence of high blood pressure.

Rick Dart, M.D., Ph.D., director of the Rocky Mountain Poison & Drug Center in Colorado, whose research is supported by McNeil Consumer & Specialty Pharmaceuticals, said, "We've administered acetaminophen to alcoholic patients and have not found any evidence of injury to their livers at all."

Dart continued, "We're seeing a higher proportion of deaths from people who take a cold preparation with acetaminophen together with regular acetaminophen or who use an opioid combination with a straight acetaminophen." Dart said education is needed to warn patients. He also cautioned that if it is difficult for patients to access acetaminophen or if consumers are frightened away from the product, they might take NSAIDs instead. "People overuse NSAIDs, too, and that leads to gastrointestinal bleeds. More people have died from nonsteroidal abuse and GI bleeding than from acetaminophen," he said.

Finally, Michael Beckerich, spokesman for McNeil, the maker of Tylenol, gave this response, "The company strongly recommends that any consumer who uses a medicine, whether an OTC medicine or a prescription medicine, read the product label and follow the dosing information. All Tylenol products contain the warning 'Do not use with any other product containing acetaminophen,'" he said.

Beckerich added that McNeil has implemented labeling and educational interventions for both consumers and healthcare providers. DT

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

JAN 8 2007

Frederick S. Mayer, R.Ph., M.P.H.
President, Pharmacists Planning Service, Inc. (PPSI)
101 Lucas Valley Road, Suite 210
San Rafael, California 94903

Re: Docket No. 2004P-0315
Comment No. CP1

Dear Mr. Mayer:

This letter responds to your citizen petition dated June 23, 2004. Your petition requests that the Food and Drug Administration (FDA) switch pseudoephedrine from over-the-counter (OTC) status to a "Pharmacists-Only" class of drugs requiring mandatory consultation, patient history review, identification, and registration. The petition was filed in the FDA Division of Dockets Management under Docket No. 2004P-0315 and logged as Comment No. CP1. For reasons discussed below, your petition is denied.

Congress reauthorized the Patriot Act of 2001 as the USA Patriot Improvement and Reauthorization Act of 2005 (PIRA). Section 701 of the PIRA includes the Combat Methamphetamine Epidemic Act of 2005 (Meth Act) which restricts the sale of pseudoephedrine, a precursor to the production of methamphetamine. The restrictions are described in detail in the Meth Act part of PIRA (copy enclosed). The PIRA was signed into law by President George W. Bush on March 9, 2006. The Meth Act, part of the PIRA, amended the Controlled Substances Act, which is under the jurisdiction of the Drug Enforcement Administration (DEA). Accordingly, the FDA has no authority to grant your request because your petition has been addressed by the Meth Act. Therefore, your petition is denied.

Any comment you wish to make on the above information should be submitted in three copies, identified with the docket and comment numbers shown at the beginning of this letter, to the Division of Dockets Management (HFA-305), Food and Drug Administration, Room 1061, 5630 Fishers Lane, Rockville, MD 20852. Additional comments may be submitted directly to the DEA.

Sincerely yours,

for

Margaret O'K. Glavin
Associate Commissioner for Regulatory Affairs

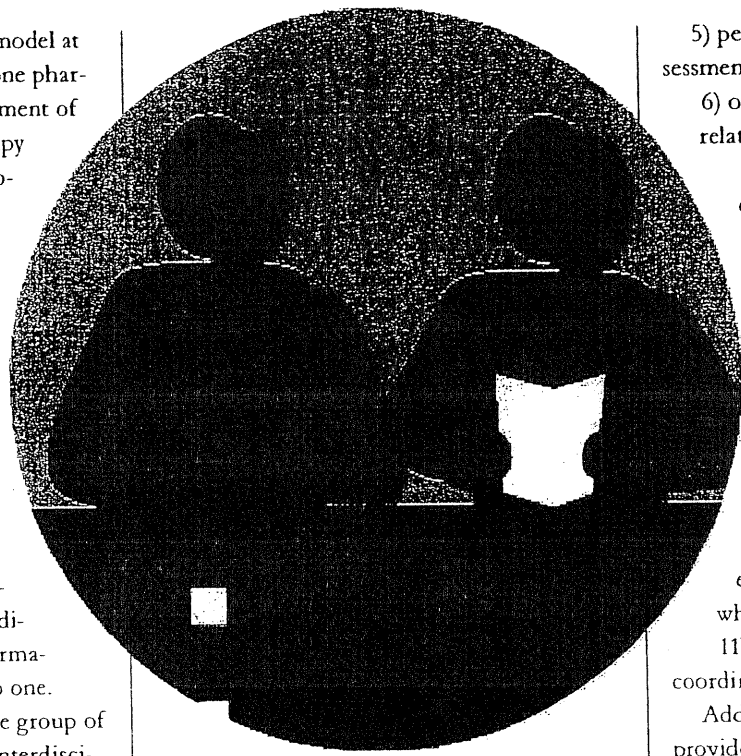
Enclosure

(60) (CP1)

Kaiser Permanente Primary Care Model: One Area's Perspective

by David Chen, Pharm. D.

The primary care pharmacist model at Kaiser Permanente (KP) is one pharmacy strategy in the management of Medicare Part D Medication Therapy Management (MTM), newer cardiovascular risk prevention programs and patients with chronic conditions to optimize HEDIS and other quality goals.



While not a novel concept, pharmacists in the primary care model work in a team environment, physically integrated with physicians, nurse practitioners, physical therapists, social workers, psychologists, clinical health educators and support staff including administrators, nurses and medical assistants. The provider to pharmacist ratio is approximately 15-20 to one. All patients managed belong to the group of physicians within the team. This interdisciplinary approach to care is coordinated by the physician of that patient. He/she provides the comprehensive health care plan that is designed, implemented and monitored by the appropriate member of the primary care team. The pharmacist's role on the team serves as the medication specialist and is involved with treatment plans that include initiating, titrating, discontinuing and monitoring of drug therapy.

Primary care pharmacists must have completed at least a one year post-graduate residency program, preferably in pharmacy practice, or have equivalent experience in direct patient care. Pharmacists work under protocol and a scope of practice. These protocols are developed in conjunction with the physicians, pharmacist managers and in accordance to national / institutional clinical guidelines to ensure appropriate care is provided to the patient. Specific language within the protocol defines the pharmacist responsibility and monitoring strategy. Primary care pharmacists will manage, under protocol, a wide variety of chronic diseases including hypertension, hyperlipidemia, diabetes, asthma, depression, thyroid disorders, and congestive heart failure in the context of attaining specific therapeutic outcomes and managing polypharmacy, non compliance and/or non formulary issues. However, as the primary care area is usually a first stop in the health care system, general medication issues or disease states require pharmacist to be versed in all areas of pharmacotherapy.

Primary care pharmacists will see patients in a setting similar to a physician exam room, communicate with the patient via phone or conduct group classes. Pharmacist to patient responsibility (medication therapy management) includes:

1) reviewing the medical record and medication profile.

2) identifying chronic medical condition and potential drug related problems.

3) developing a medication treatment plan,

4) assessing the patient's knowledge of medication/disease, medication compliance, adverse effects, drug interactions, and lifestyle modification.

5) performing appropriate physical assessments related to medication therapy.

6) ordering appropriate laboratory test(s) related to medication therapy.

7) selecting, initiating, modifying, discontinuing medication(s) per protocol.

8) monitoring and evaluating for adverse effects, complications, and therapeutic outcomes.

9) providing and reinforcing patient education / information designed to enhance patient understanding and patient adherence.

10) referring to other health care professionals within the broader health care management services, when appropriate.

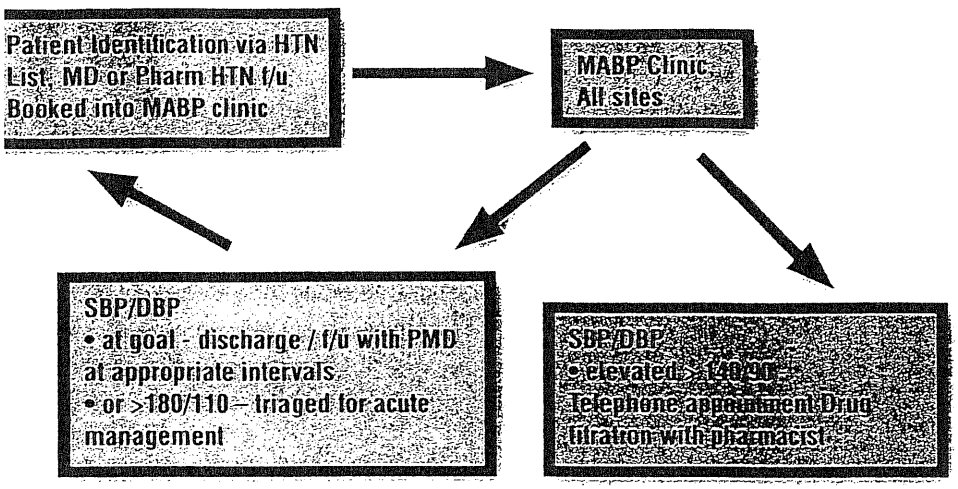
11) documenting, communicating and coordinating medication therapy issues.

Additionally, primary care pharmacists provide drug information to the rest of the members of the team, assist in the management of formulary, cost effective prescribing and resolve operational pharmacy medication-related problems.

Patients are referred to the pharmacist by the physician to address any type of medication questions, pharmacy related issues, adverse drug reactions, as well as for management of chronic condition through a number of primary care team workflows. A primary care pharmacist, throughout the workday, can receive any number or diverse type of patient care medication issues for resolution or any type of physician referral. This requires they be flexible, efficient, versatile and autonomous in managing their own practice.

The first example is one type of patient referral that is simple and straightforward, demonstrating the collaboration of care by different primary care team members. A Medical Assistant Blood Pressure clinic (MABP) utilizes the strengths of the individual primary care team members to integrate and develop a potentially more time-efficient hypertension clinic.

In the Northern California area, patients



ı hypertension or identified via computer aving elevated systolic/diastolic blood ssures or without a documented reading he past year are scheduled to see a medical stant. At the visit, patients obtain a blood ssure reading, pulse and a medication his- . In the event that the BP is greater than /110, the patient is automatically triaged charge nurse and physician for acute nagement of hypertension. If the blood ssure is between 140/90 and 180/110, ysician referral is generated for the rmacist to manage the hypertension. By ne, the pharmacist will verify the medi- on history previously provided by the ient, perform an assessment of medication pliance and lifestyle modifications, de- p a treatment plan, initiate/modify cur- t medication therapy, provide drug con- ation, ensure understanding and establish ropriate follow up, i.e. return to MABP ic and document in the medical record. If patient returns to the MABP clinic and tinues to be elevated, the cycle repeats. If patient improves to the therapeutic goal, patient is discharged out of the clinic for ow up by the physician without needing see the pharmacist. Three to four patients be managed per hour while utilizing the ngths of the primary team members to nage hypertensive patients cost-efficiently. sults of a six month pre-to post-pharmacist olvement reveals average blood pres- es were reduced from 150/83 to 125/79 h over 650 patients completely managed. ile it is possible to hire the above person- nel into a stand alone hypertension clinic, the advantage to the primary care model provides disease state variety to the pharmacist, patient familiarity and the time and ability to review medication profiles for additional medication issues that need attention.

Another example of integrated care via primary care model can be seen conceptually in a Antidepressant Medication Management program. HEDIS requires Optimum Practitioner Contact (defined as at least 3 follow up visits with a physician or mental health provider within the first 12 weeks of acute treatment), Effective Acute Phase Treatment (medication compliance within 12 weeks) and Effective Continuation Phase Treatment (medication compliance within 6 months) after a new episode of depression. Most patients diagnosed with depression/anxiety are managed in primary care with more complex cases referred to psychiatry. Using the primary care model approach, the pharmacist works alongside the physician, social workers and psychologists to ensure that the patient is compliant with the optimal practitioner contact criteria. He/she provides medication therapy management and coordinates drug therapy with the behavioral, non-drug counseling and lifestyle modifications provided by the other team members. The ultimate objective is to ensure adherence to medication therapy by monitoring and evaluating for adverse effects, complications, therapeutic outcomes, and adjusting therapy as necessary.

Primary care pharmacists work closely with pharmacy operations and are very active members of their team. They attend department team meetings, develop clinical programs with other team members and will provide a cost effective pharmacotherapy approach to care. They provide education regarding new approved medications, preferred agents, formulary changes, media balance and update the team on possible supply chain issues. For the patients having trouble affording medications, the primary care pharmacists uses this knowledge to provide a necessary service to help address cost issues and ensuring compliance to changes in therapy.

Medication Therapy Management in Medicare Part D at Kaiser Permanente is the culmination of all pharmacy programs and models well into the primary care pharmacist model. MTM at KP consists of identifying patients with chronic conditions; chronic medications and a $4000 drug expenditure. These patients have multiple medical problems and have a potential to be at personal cost risk. MTM services include reviewing diagnoses, laboratory services, medications, immunization and social history and evaluating for duplicative therapy, drug-drug interactions, drug-disease interactions, adherence issues, multiple prescribers, drugs that are potentially problematic in elderly, therapy gaps, and opportunities to reduce cost. MTM patients are divided up amongst the primary care pharmacists by the physician of the patient. Similarly, with a coordinated approach, patients are referred by the physician for management and the pharmacist will address the previous medications issues. Given the wide experience of managed chronic conditions, and often, familiarity with the complicated patients, primary care pharmacists are then capable to carry forward the recommendations to optimize patient medication issues, optimize therapeutic outcomes and refer to team members or specialists for further care.

David Chen, Pharm. D. is the Clinical Operations Manager of Kaiser Permante in the Napa-Solano Service Area.

R.Ph.s chafe under systems that time their dispensing

Reid Paul

As reimbursements for drugs keep falling, chains must fill more prescriptions—and apply even more pressure on their pharmacists to dispense quickly—to make up for their loss. But pharmacists claim this is leading to more drug errors.

The practice of timing pharmacists on how quickly they fill prescriptions is increasingly being called into question. One national chain, for instance, uses a red light on their pharmacists' computer screens to warn them if they are falling behind in their dispensing.

"My main concern is with the impact on staffing and the profession," commented Charles L. Duhon, R.Ph., a community pharmacist who practices in Oklahoma. "You feel like the guy behind the hotdog stand. It is all money, money, money, as fast as you can."

Duhon is particularly concerned about the effect on young pharmacists who come to pharmacy as idealists and leave embittered. "Most pharmacy students are not aware what they will be facing when they get out of school," he said.

Kaiser Permanente has had a standard of filling each new prescription within 15 minutes for more than six years, noted Steven Gray, Pharm.D., J.D., who heads professional affairs for the HMO's pharmacy operations. "The service standard is for the entire pharmacy operation," he explained. "Eighty percent of prescriptions should be filled within 15 minutes."

The goal, Gray said, is not to single out pharmacists who do not meet the standard, but rather to focus on how the pharmacy can be improved to produce efficiently. "If a pharmacy starts to fall below standard, we send in a pharmacy improvement team [PIT]," he explained. The team works with management and staff to see what the problem is. Based on PIT recommendations, Kaiser may hire additional staff for the pharmacy or change procedures to meet the pharmacy standard.

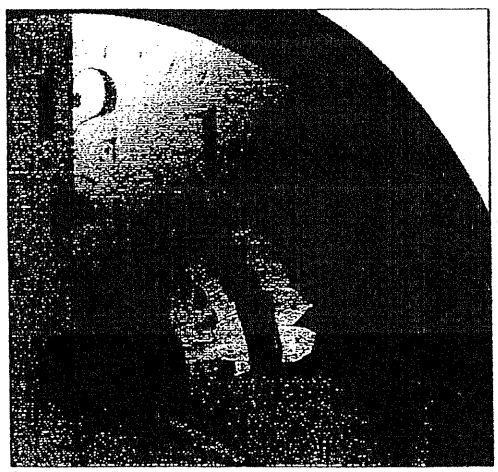


Photo: PhotoDisc

Kaiser said its 15-minute rule came out of surveys of pharmacy patients. "We find a correlation between member satisfaction and the waiting time," Gray reported.

Kaiser maintains that automated refills and training are key ingredients for meeting the service standard. The vast majority of refills are handled at centralized robotic fill centers. Furthermore, with e-prescribing, prescriptions are often started before patients even enter the pharmacy. The Kaiser HMO model with the physicians and pharmacy under the same roof also helps to increase efficiency and reduce the time pharmacists spend on the phone. "In my opinion it is the most forward-looking pharmacy group in the nation, ahead of most everyone," said one current Kaiser pharmacist who asked not to be identified.

"It is such an efficient organization. On a typical day, you'd work behind the counter dispensing medications for an hour then consult for an hour," the Kaiser pharmacist explained. "It's not like a factory assembly line." Still, he went on to note that pharmacists are judged daily based on their speed.

It is that judging that causes concern for many observers and raises questions about the value of such time-based service standards. And while many observers agreed that Kaiser is respected for its efficiency, similar workplace standards that exist at several large chain pharmacies are troubling. "We are concerned about prescription errors and the impact on consumers," insisted Fred S. Mayer, R.Ph., M.P.H., president, Pharmacists Planning Service Inc. (PPSI), a pharmacy-related consumer advocacy group. "If you believe the studies, pharmacists should not be filling more than 180 prescriptions per shift."

Some drugs, especially those with black box warnings, may need extra time, Mayer argued, and timers place an undue pressure on pharmacists to focus more on time than on patient safety. While he admitted that Kaiser Permanente's pharmacy operations may be able to handle the volume, he worries that at other chain pharmacies, the same safeguards and quality control mechanisms may not be as stringent.

In all likelihood, this debate over the efficacy, safety, and professional impact of timed service standards will only continue as the practice spreads. "What we need to do," Duhon demanded, "is get together to change the system." DT

Improving the California Pharmacist/Patient Consultation Proc

In collaboration with the California Board of Pharmacy, the California Pharmacists Association, and California AARP, the Center for Health Improvement (CHI) recently completed a two-year study (2004-2005) that examined the mandated pharmacist-patient consultation process and its effects on Californians aged 65 and older. The focus on seniors was important since persons aged 65 and older are prescribed twice as many medications as those under 65. Approximately 90 percent of older persons take at least one prescription drug, and nearly half use five or more different drugs. Additionally, older adults have more chronic diseases and multiple conditions, thus the consultation process becomes more relevant and complex.

The following provides a summary of the CHI study:

The Institute of Medicine recently raised the issue of medical errors overall, and determined that prescription drugs are a significant source of such errors. That, combined with the above statistics and the fact that an analysis of adverse drug events (ADEs) among older adults in an ambulatory setting indicated that 27.6 percent of the documented ADEs were *preventable*, prompted the selection of the older adult population for the pharmacist-patient consultation study.

Federal and State Mandate

In August 1990, the Board of Pharmacy enacted regulations requiring pharmacist-patient consultation for all new or changed prescriptions. These regulations preceded the federal mandate and were also more stringent (the federal mandate required offering to counsel Medicaid recipients upon receipt of a new prescription). The regulations were enacted to ensure that the necessary dialogue occurs between patients and medication experts to promote safe and effective medication use. The only California study to examine the effectiveness of the counseling regulations was conducted in the early 1990s.

Study Methodology

The CHI study consisted of:

1. A literature review;
2. A review of Board inspection and complaint data;
3. A statewide survey of pharmacists. The written survey of pharmacists involved sampling 3,000 of the approximately 5,000 California-licensed community pharmacies. A 32.4 percent response rate was achieved, and the independent/chain pharmacy ratio was 45.4 percent to 54.6 percent. Kaiser Foundation outpatient pharmacies were also included in the stud
4. Focus groups of pharmacists, physicians and patients; and
5. A policy roundtable discussio

Key Areas for Improving Consultati

The CHI study found two key areas of consultation were noted by respondents as requiring improvement the first being that **pharmacist time a insufficient compensation** specific to consultation were identified as critical barriers to maximizing the pharmacist patient consultation. Non-compensate time-consuming activities include, am others, the requirement for pharmacist to submit a prescription for insurance approval, only to be notified of the ne for prior authorization. The pharmacis then required to contact the prescribin physician. As formularies become mo complex, pharmacists electronically transmit information for prescription approval. Pharmacies are charged for transmittals, and if the prescription is covered by the formulary, the pharma are not reimbursed for the transmittal

Time and Compensation Recommendations

- Consider changing the pharmacis pharmacy technician ratio, which is currently 1:1 with two pharmacy technicians allowed fo each additional pharmacist in the pharmacy. The National Associat of Boards of Pharmacy surveyed pharmacists and found that "havi more technicians available to assi with dispensing duties would inc pharmacist time for counseling."

- Continue to examine California regulations that might discourage use of technology. The promotion technology should not have to co at the expense of pharmacists but free them from administrative an other activities.

Create financial incentives based pharmacists' performance. As

Improving Consult Process

Continued from Page 16

is occurring with hospitals and physicians, financial incentives awarded to pharmacists can encourage continued quality improvement. Performance measures could include patient satisfaction, dispensing efficiency, and additional services such as medication compliance monitoring, disease management counseling, and medication profile review.

Pharmacist/Patient and Pharmacist/ Physician Communication

The CHI also found that another significant barrier to maximizing the consultation process is **pharmacist-patient communication, as well as pharmacist-physician communication.** Before the pharmacist can successfully communicate with the patient, the patient must be educated about the process of navigating formulary issues, communicating with the physician, understanding the time needed for prior authorization and coordination with changing formularies. Patients need to understand the importance of the clinical information that pharmacists provide, and that **patient participation in the consultation is critical.** Nearly a quarter of the survey respondents rated the "patient's refusal to participate" as a significant barrier. Survey results showed that 50 percent of older patients waived the consultation—answering the survey with "sometimes," "often" or " always."

The survey results revealed that nearly a third of the pharmacist respondents spend 10-25 percent of their time communicating with physicians. That communication is inefficient at best: sending and receiving faxes, calling and leaving messages. Both pharmacists and physicians described their frustration with these activities and noted that better patient care required better communication.

See **Improving Consult Process**, Page 18

Where to Find Answers to Your Legal Questions

Pharmacy law is detailed and complicated. The Board strongly encourages licensees to seek out answers to their legal questions by accessing pharmacy law.

Licensees of the Board have a number of choices when they seek to obtain copies of pharmacy law.

1. The Board has on its Web site a copy of all California pharmacy laws and regulations. The address is *www.pharmacy.ca.gov/laws_regs/lawbook.pdf.*

There are several advantages of using this source for pharmacy law. It is free. It also contains a detailed index, developed and used by board staff, which is not published in either of the following lawbooks.

2. LawTech, who has published our lawbook for the last six years, offers a lawbook (Pharmacy Law with Rules and Regulations) and a CD version for sale. Ordering information is available via a link from the Board's Web site or by calling 1-800-498-0911 X 5.

The cost for this lawbook is $21.99. The CD version is also $21.99.

3. LexisNexis has also produced its first version of our lawbook (California Pharmacy Laws with Rules and Regulations). Again, there is also a CD version of this publisher's lawbook. You may order by calling 1-800-833-9844.

This lawbook alone is available for $17, and the lawbook with the CD is $22.

What about prescriptions written by prescribers in Mexico?

In March 2006, California's third-largest health insurer, Health Net, announced that it plans to sell policies that allow individuals or families to see doctors in the U.S. or in Mexico. This development raises questions:

Q. **Can a California pharmacist fill a prescription for a California Health Net patient based on a prescription written by a doctor licensed to practice in Mexico?**

A. No. Section 1717(d) of the California Code of Regulations stipulates that a pharmacist may dispense pursuant to a prescription written by "...a prescriber licensed in a state other than California," which means a state (not a territory or possession) within the United States, not a foreign country.

Q. **Can a California pharmacist fill a prescription written by a prescriber who is licensed to prescribe in California or another state, but practicing in Mexico?**

A. Yes, as long as the prescriber is licensed in the same licensure classification that California law permits to prescribe drugs. It is, of course, the pharmacist's responsibility to verify the prescriber's license with the respective regulatory board of the state where the prescriber is licensed.

For complete details, please see full prescribing information for Lexapro.

Children and Adolescents Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of Lexapro or any other antidepressant in a child or -d balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Lexapro is not in pediatric patients. (See Warnings and Precautions: Pediatric Use) Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psy- a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, risk of 2%. No suicides occurred in these trials.

ONS Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated (see **WARNINGS**). Concomitant use in patients taking pimozide is contraindicated (see **Drug Interactions – Pimozide and Celexa**). Lexapro is contraindicated in patients with a hypersensitivity to escitalopram or citalopram ive ingredients in Lexapro. **WARNINGS WARNINGS-Clinical Worsening and Suicide Risk Clinical Worsening and Suicide Risk** Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. There has been a long-standing concern that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients. Antidepressants increased al thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Pooled analyses of short-term placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with MDD, OCD, or other psychi- total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal behavior or thinking (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo was considerable variation in risk among drugs, but a tendency toward an increase for almost all drugs studied. The risk of suicidality was most consistently observed in the MDD trials, but there were signals of risk arising from some trials in other psychiatric indications (obsessive compulsive disorder and social anxiety ell. **No suicides occurred in any of these trials.** It is unknown whether the suicidality risk in pediatric patients extends to longer-term use, i.e., beyond several months. It is also unknown whether the suicidality risk extends to adults. **All pediatric patients being treated with antidepressants for any indication should be osely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases. Such observation would generally include at least weekly face-to-face contact with patients or their family mem- egivers during the first 4 weeks of treatment, then every other week visits for the next 4 weeks, then at 12 weeks, and as clinically indicated beyond 12 weeks. Additional contact by telephone may be appropriate between face-to-face visits. Adults with MDD or co-morbid depression in the setting of other psychiatric g treated with antidepressants should be observed similarly for clinical worsening and suicidality, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.** The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, ess, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and nonpsychiatric. Although a causal link between the emergence of such symp- ther the worsening of depression and/or the emergence of suicidal impulses has not been established, there is concern that such symptoms may represent precursors to emerging suicidality. Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms. If the decision has been made to discontinue treatment, medication apered, as rapidly as is feasible, but with recognition that abrupt discontinuation can be associated with certain symptoms (see **PRECAUTIONS and DOSAGE AND ADMINISTRATION—Discontinuation of Treatment with Lexapro, in full prescribing information for a description of the risks of discontinuation of Lexapro). d caregivers of pediatric patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and the other symptoms described vell as the emergence of suicidality, and to report such symptoms immediately to health care providers. Such monitoring should include daily observation by families and caregivers.** Prescriptions for Lexapro should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce verdose. Families and caregivers of adults being treated for depression should be similarly advised. **Screening Patients for Bipolar Disorder:** A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with an ant alone may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. Whether any of the symptoms described above represent such a conversion is unknown. However, prior to initiating treatment with an antidepressant, patients with depressive symptoms should be adequately determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. It should be noted that Lexapro is not approved for use in treating bipolar depression. **Potential for Interaction with Monoamine Oxidase Inhibitors receiving serotonin reuptake inhibitor drugs in combination with a monoamine oxidase inhibitor (MAOI), there have been reports of serious, sometimes fatal, reactions including hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, and mental status changes that reme agitation progressing to delirium and coma. These reactions have also been reported in patients who have recently discontinued SSRI treatment and have been started on an MAOI. Some cases presented with features resembling neuroleptic malignant syndrome. Furthermore, limited animal data on the effects d use of SSRIs and MAOIs suggest that these drugs may act synergistically to elevate blood pressure and evoke behavioral excitation. Therefore, it is recommended that Lexapro should not be used in combination with an MAOI, or within 14 days of discontinuing treatment with an MAOI. Similarly, at least 14 days llowed after stopping Lexapro before starting an MAOI. Serotonin syndrome has been reported in two patients who were concomitantly receiving linezolid, an antibiotic which is a reversible non-selective MAOI.** ***Serotonin Syndrome:*** The development of a potentially life-threatening serotonin syndrome may occur with SSRIs, including Lexapro treatment, particularly with concomitant use of serotonergic drugs (including triptans) and with drugs which impair metabolism of serotonin (including MAOIs). Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachy- e blood pressure, hyperthermia), neuromuscular aberrations (e.g., hyperreflexia, incoordination) and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). The concomitant use of Lexapro with MAOIs intended to treat depression is contraindicated (see **CONTRAINDICATIONS** and **WARNINGS - Potential for Interaction mine Oxidase Inhibitors.**) If concomitant treatment of Lexapro with a 5-hydroxytryptamine receptor agonist (triptan) is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases (see **PRECAUTIONS - Drug Interactions**). The concomitant use of Lexapro with sero- rsors (such as tryptophan) is not recommended (see **PRECAUTIONS - Drug Interactions**). **PRECAUTIONS** Information for Patients Patients should be cautioned about the risk of serotonin syndrome with the concomitant use of Lexapro and triptans, tramadol or other serotonergic agents. Drug Interactions *Serotonergic Drugs:* e mechanism of action of SNRIs and SSRIs including Lexapro, and the potential for serotonin syndrome, caution is advised when Lexapro is coadministered with other drugs that may affect the serotonergic neurotransmitter systems, such as triptans, linezolid (an antibiotic which is a reversible non-selective MAOI), lithium, tra- St. John's Wort (see **WARNINGS - Serotonin Syndrome**). The concomitant use of Lexapro with other SSRIs, SNRIs or tryptophan is not recommended (see **PRECAUTIONS - Drug Interactions**). *Triptans:* There have been rare postmarketing reports of serotonin syndrome with use of an SSRI and a triptan. If concomitant treat- xapro with a triptan is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases (see **WARNINGS - Serotonin Syndrome**). **General** Discontinuation of Treatment with Lexapro During marketing of Lexapro and other SSRIs and SNRIs (serotonin and norepineph- e inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethar- al lability, insomnia, and hypomania. While these events are generally self-limiting, there have been reports of serious discontinuation symptoms. Patients should be monitored for these symptoms when discontinuing treatment with Lexapro. A gradual reduction in the dose rather than abrupt cessation is recommended when- le. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate (see **DOSAGE AND ADMINISTRATION** in full prescribing informa- rmal Bleeding Published case reports have documented the occurrence of bleeding episodes in patients treated with psychotropic drugs that interfere with serotonin reuptake. Subsequent epidemiological studies, both of the case-control and cohort design, have demonstrated an association between use of psychotropic drugs re with serotonin reuptake and the occurrence of upper gastrointestinal bleeding. In two studies, concurrent use of a nonsteroidal anti-inflammatory drug (NSAID) or aspirin potentiated the risk of bleeding (see **Drug Interactions**). Although these studies focused on upper gastrointestinal bleeding, there is reason to believe that other sites may be similarly potentiated. Patients should be cautioned regarding the risk of bleeding associated with the concomitant use of Lexapro with NSAIDs, aspirin, or other drugs that affect coagulation. Hyponatremia Cases of hyponatremia and SIADH (syndrome of inappropriate antidiuretic hormone secretion) have been association with Lexapro treatment. All patients with these events have recovered with discontinuation of escitalopram and/or medical intervention. Hyponatremia and SIADH have also been reported in association with other marketed drugs effective in the treatment of major depressive disorder. Activation of Mania/Hypomania controlled trials of Lexapro in major depressive disorder, activation of mania/hypomania was reported in one (0.1%) of 715 patients treated with Lexapro and in none of the 592 patients treated with placebo. One additional case of hypomania has been reported in association with Lexapro treatment. Activation of mania/hypoma- o been reported in a small proportion of patients with major affective disorders treated with racemic citalopram and other marketed drugs effective in the treatment of major depressive disorder. As with all drugs effective in the treatment of major depressive disorder, Lexapro should be used cautiously in patients with a history Seizures Although anticonvulsant effects of racemic citalopram have been observed in animal studies, Lexapro has not been systematically evaluated in patients with a seizure disorder. These patients were excluded from clinical studies during the product's premarketing testing. In clinical trials of Lexapro, cases of convulsion reported in association with Lexapro treatment. Like other drugs effective in the treatment of major depressive disorder, Lexapro should be introduced with care in patients with a history of seizure disorder. Interference with Cognitive and Motor Performance In a study in normal volunteers, Lexapro 10 mg/day did not produce t of intellectual function or psychomotor performance. Because any psychoactive drug may impair judgment, thinking, or motor skills, however, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that Lexapro therapy does not affect their ability to engage ivities. Use in Patients with Concomitant Illness Clinical experience with Lexapro in patients with certain concomitant systemic illnesses is limited. Caution is advisable in using Lexapro in patients with diseases or conditions that produce altered metabolism or hemodynamic responses. Lexapro has not been systematically eval- tients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were generally excluded from clinical studies during the product's premarketing testing. In subjects with hepatic impairment, clearance of racemic citalopram was decreased and plasma concentrations were increased. The ded dose of Lexapro in hepatically impaired patients is 10 mg/day (see **DOSAGE AND ADMINISTRATION** in full prescribing information). Because escitalopram is extensively metabolized, excretion of unchanged drug in urine is a minor route of elimination. Until adequate numbers of patients with severe renal impairment have ated during chronic treatment with Lexapro, however, it should be used with caution in such patients (see **DOSAGE AND ADMINISTRATION** in full prescribing information). **Drug Interactions** CNS Drugs - Given the primary CNS effects of escitalopram, caution should be used when it is taken in combination with other centrally s. Alcohol - Although Lexapro did not potentiate the cognitive and motor effects of alcohol in a clinical trial, as with other psychotropic medications, the use of alcohol by patients taking Lexapro is not recommended. Monoamine Oxidase Inhibitors (MAOIs) - See **CONTRAINDICATIONS** and **WARNINGS**. **Drugs That Interfere With s (NSAIDs, Aspirin, Warfarin, etc.)** Serotonin release by platelets plays an important role in hemostasis. Epidemiological studies of the case-control and cohort design that have demonstrated an association between use of psychotropic drugs that interfere with serotonin reuptake and the occurrence of upper gastrointestinal ave also shown that concurrent use of an NSAID or aspirin potentiated the risk of bleeding. Thus, patients should be cautioned about the use of such drugs concurrently with Lexapro. Cimetidine - In subjects who had received 21 days of 40 mg/day racemic citalopram, combined administration of 400 mg/day cimetidine for 8 ted in an increase in citalopram AUC and C_{max} of 43% and 39%, respectively. The clinical significance of these findings is unknown. Digoxin - In subjects who had received 21 days of 40 mg/day racemic citalopram, combined administration of citalopram and digoxin (single dose of 1 mg) did not significantly affect the pharma- of either citalopram or digoxin. Lithium - Coadministration of racemic citalopram (40 mg/day for 10 days) and lithium (30 mmol/day for 5 days) had no significant effect on the pharmacokinetics of citalopram or lithium. Nevertheless, plasma lithium levels should be monitored with appropriate adjustment to the lithium dose in e with standard clinical practice. Because lithium may enhance the serotonergic effects of escitalopram, caution should be exercised when Lexapro and lithium are coadministered. Pimozide and Celexa - In a controlled study, a single dose of pimozide 2 mg co-administered with racemic citalopram 40 mg given once daily for 11 ssociated with a mean increase in QTc values of approximately 10 msec compared to pimozide given alone. Racemic citalopram did not alter the mean AUC or C_{max} of pimozide. The mechanism of this pharmacodynamic interaction is not known. Sumatriptan - There have been rare postmarketing reports describing patients with hyperreflexia, and incoordination following the use of an SSRI and sumatriptan. If concomitant treatment with sumatriptan and an SSRI (e.g., fluoxetine, fluvoxamine, paroxetine, sertraline, citalopram, escitalopram) is clinically warranted, appropriate observation of the patient is advised. Theophylline - Combined administration citalopram (40 mg/day for 21 days) and the CYP1A2 substrate theophylline (single dose of 300 mg) did not affect the pharmacokinetics of theophylline. The effect of theophylline on the pharmacokinetics of citalopram was not evaluated. Warfarin - Administration of 40 mg/day racemic citalopram for 21 days did not affect the inetics of warfarin, a CYP3A4 substrate. Prothrombin time was increased by 5%, the clinical significance of which is unknown. Carbamazepine - Combined administration of racemic citalopram (40 mg/day for 14 days) and carbamazepine (titrated to 400 mg/day for 35 days) did not significantly affect the pharmacokinetics of pine, a CYP3A4 substrate. Although trough citalopram plasma levels were unaffected, given the enzyme-inducing properties of carbamazepine, the possibility that carbamazepine might increase the clearance of escitalopram should be considered if the two drugs are coadministered. Triazolam - Combined administration of racemic (titrated to 40 mg/day for 28 days) and the CYP3A4 substrate triazolam (single dose of 0.25 mg) did not significantly affect the pharmacokinetics of either citalopram or triazolam. Ketoconazole - Combined administration of racemic citalopram (40 mg) and ketoconazole (200 mg), a potent CYP3A4 inhibitor, decreased the C_{max} f ketoconazole by 21% and 10%, respectively, and did not significantly affect the pharmacokinetics of citalopram. Ritonavir - Combined administration of a single dose of ritonavir (600 mg), both a CYP3A4 substrate and a potent inhibitor of CYP3A4, and escitalopram (20 mg) did not affect the pharmacokinetics of either riton- italopram. CYP3A4 and -2C19 Inhibitors - *In vitro* studies indicated that CYP3A4 and -2C19 are the primary enzymes involved in the metabolism of escitalopram. However, coadministration of escitalopram (20 mg) and ritonavir (600 mg), a potent inhibitor of CYP3A4, did not significantly affect the pharmacokinetics of escitalo- ause escitalopram is metabolized by multiple enzyme systems, inhibition of a single enzyme may not appreciably decrease escitalopram clearance. Drugs Metabolized by Cytochrome P4502D6 - *In vitro* studies did not reveal an inhibitory effect of escitalopram on CYP2D6. In addition, steady state levels of racemic citalopram were cantly different in poor metabolizers and extensive CYP2D6 metabolizers after multiple-dose administration of citalopram, suggesting that coadministration, with escitalopram, of a drug that inhibits CYP2D6, is unlikely to have clinically significant effects on escitalopram metabolism. However, there are limited *in vivo* data sug- modest CYP2D6 inhibitory effect for escitalopram, i.e., coadministration of escitalopram (20 mg/day for 21 days) with the tricyclic antidepressant desipramine (single dose of 50 mg), a substrate for CYP2D6, resulted in a 40% increase in C_{max} and a 100% increase in AUC of desipramine. The clinical significance of this finding is Nevertheless, caution is indicated in the coadministration of escitalopram and drugs metabolized by CYP2D6. Metoprolol - Administration of 20 mg/day Lexapro for 21 days in healthy volunteers resulted in a 50% increase in C_{max} and 82% increase in AUC of the beta-adrenergic blocker metoprolol (given in a single dose of 100 ased metoprolol plasma levels have been associated with decreased cardioselectivity. Coadministration of Lexapro and metoprolol had no clinically significant effects on blood pressure or heart rate. Electroconvulsive Therapy (ECT) - There are no clinical studies of the combined use of ECT and escitalopram. **Carcinogenesis, sis, Impairment of Fertility** Carcinogenesis Racemic citalopram was administered in the diet to NMRI/BOM strain mice and COBS WI strain rats for 18 and 24 months, respectively. There was no evidence for carcinogenicity of racemic citalopram in mice receiving up to 240 mg/kg/day. There was an increased incidence of small arcinoma in rats receiving 8 or 24 mg/kg/day racemic citalopram. A no-effect dose for this finding was not established. The relevance of these findings to humans is unknown. Mutagenesis Racemic citalopram was mutagenic in the *in vitro* bacterial reverse mutation assay (Ames test) in 2 of 5 bacterial strains (Salmonella TA98 37) in the absence of metabolic activation. It was clastogenic in the *in vitro* Chinese hamster lung cell assay for chromosomal aberrations in the presence and absence of metabolic activation. Racemic citalopram was not mutagenic in the *in vitro* mammalian forward gene mutation assay (HPRT) in mouse lymphoma cells or in a vitro/in vivo unscheduled DNA synthesis (UDS) assay in rat liver. It was not clastogenic in the *in vitro* chromosomal aberration assay in human lymphocytes or in two *in vivo* mouse micronucleus assays. Impairment of Fertility When racemic citalopram was administered orally to 16 male and 24 female rats prior to and through- and gestation at doses of 32, 48, and 72 mg/kg/day, mating was decreased at all doses, and fertility was decreased at doses ≥ 32 mg/kg/day. Gestation duration was increased at 48 mg/kg/day. **Pregnancy-Nonteratogenic Effects** Neonates exposed to Lexapro and other SSRIs or SNRIs, late in the third trimester, have developed ions requiring prolonged hospitalization, respiratory support, and tube feeding. Such complications can arise immediately upon delivery. Reported clinical findings have included respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypotonia, hypertonia, hyperreflexia, teriness, irritability, and constant crying. These features are consistent with either a direct toxic effect of SSRIs and SNRIs or, possibly, a drug discontinuation syndrome. It should be noted that, in some cases, the clinical picture is consistent with serotonin syndrome (see **WARNINGS**). Infants exposed to SSRIs in late pregnancy an increased risk for persistent pulmonary hypertension of the newborn (PPHN). PPHN occurs in 1-2 per 1000 live births in the general population and is associated with substantial neonatal morbidity and mortality. In a retrospective, case-control study of 377 women whose infants were born with PPHN and 836 women whose re born healthy, the risk for developing PPHN was approximately six-fold higher for infants exposed to SSRIs after the 20th week of gestation compared to infants who had not been exposed to antidepressants during pregnancy. There is currently no corroborative evidence regarding the risk for PPHN following exposure to SSRIs cy; this is the first study that has investigated the potential risk. The study did not include enough cases with exposure to individual SSRIs to determine if all SSRIs posed similar levels of PPHN risk. When treating a pregnant woman with Lexapro during the third trimester, the physician should carefully consider both the poten- nd benefits of treatment (see **DOSAGE AND ADMINISTRATION** in full prescribing information). Physicians should note that in a prospective longitudinal study of 201 women with a history of major depression who were euthymic at the beginning of pregnancy, women who discontinued antidepressant medication during preg- re more likely to experience a relapse of major depression than women who continued antidepressant medication. **Labor and Delivery** The effect of Lexapro on labor and delivery in humans is unknown. **Nursing Mothers** Racemic citalopram, like many other drugs, is excreted in human breast milk. There have been two reports experiencing excessive somnolence, decreased feeding, and weight loss in association with breastfeeding from a citalopram-treated mother; in one case, the infant was reported to recover completely upon discontinuation of citalopram by its mother and, in the second case, no follow-up information was available. The decision o continue or discontinue either nursing or Lexapro therapy should take into account the risks of citalopram exposure for the infant and the benefits of Lexapro treatment for the mother. **Pediatric Use** Safety and effectiveness in the pediatric population have not been established (see **BOX WARNING** and **WARNINGS—Clinical g and Suicide Risk**). One placebo-controlled trial in 264 pediatric patients with MDD has been conducted with Lexapro, and the data were not sufficient to support a claim for use in pediatric patients. Anyone considering the use of Lexapro in a child or adolescent must balance the potential risks with the clinical need. **Geriatric** oximately 6% of the 1144 patients receiving escitalopram in controlled trials of Lexapro in major depressive disorder and GAD were 60 years of age or older; elderly patients in these trials received daily doses of Lexapro between 10 and 20 mg. The number of elderly patients in these trials was insufficient to adequately assess for ifferential efficacy and safety measures on the basis of age. Nevertheless, greater sensitivity of some elderly individuals to effects of Lexapro cannot be ruled out. In two pharmacokinetic studies, escitalopram half-life was increased by approximately 50% in elderly subjects as compared to young subjects and C_{max} was unchanged **ICAL PHARMACOLOGY**). 10 mg/day is the recommended dose for elderly patients (see **DOSAGE AND ADMINISTRATION** in full prescribing information). Of 4422 patients in clinical studies of racemic citalopram, 1357 were 60 and over, 1034 were 65 and over, and 457 were 75 and over. No overall differences in safety or effec- vere observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but again, greater sensitivity of some elderly individuals cannot be ruled out. **ADVERSE REACTIONS** Adverse event information for Lexapro was from 715 patients with major depressive disorder who were exposed to escitalopram and from 592 patients who were exposed to placebo in double-blind, placebo-controlled trials. An additional 284 patients with major depressive disorder were newly exposed to escitalopram in open-label trials. The adverse event information for patients with GAD was collected from 429 patients exposed to escitalopram and from 427 patients exposed to placebo in double-blind, placebo-controlled trials. Adverse events during exposure were obtained primarily by general inquiry and recorded by clinical investigators using terminology of their own choosing. Consequently, ossible to provide a meaningful estimate of the proportion of individuals experiencing adverse events without first grouping similar types of events into a smaller number of standardized event categories. In the tables and tabulations that follow, standard World Health Organization (WHO) terminology has been used to classify adverse events. The stated frequencies of adverse events represent the proportion of individuals who experienced, at least once, a treatment-emergent adverse event of the type listed. An event was considered treatment-emergent if it occurred for the first time or worsened while receiving therapy following baseline evaluation. **Events Associated with Discontinuation of Treatment Major Depressive Disorder** Among the 715 depressed patients who received Lexapro in placebo-controlled trials, 6% discontinued treatment due to an adverse event, as compared to 2% of 592 patients receiving placebo. In two fixed-dose studies, the rate of discontinuation e events in patients receiving 10 mg/day Lexapro was not significantly different from the rate of discontinuation for adverse events in patients receiving placebo. The rate of discontinuation for adverse events in patients assigned to a fixed dose of 20 mg/day Lexapro was 10%, which was significantly different from the rate of dis- ion for adverse events in patients receiving 10 mg/day Lexapro (4%) and placebo (3%). Adverse events that were associated with the discontinuation of at least 1% of patients treated with Lexapro, and for which the rate was at least twice that of placebo, were nausea (2%) and ejaculation disorder (2% of male patients). **Generalized lisorder** Among the 429 GAD patients who received Lexapro 10-20 mg/day in placebo-controlled trials, 8% discontinued treatment due to an adverse event, as compared to 4% of 427 patients receiving placebo. Adverse events that were associated with the discontinuation of at least 1% of patients treated with Lexapro, and for rate was at least twice the placebo rate, were nausea (2%), insomnia (1%), and fatigue (1%). **Incidence of Adverse Events in Placebo-Controlled Clinical Trials Major Depressive Disorder** Table 1 enumerates the incidence, rounded to the nearest percent, of treatment-emergent adverse events that occurred among 715 depressed who received Lexapro at doses ranging from 10 to 20 mg/day in placebo-controlled trials. Events included are those occurring in 2% or more of patients treated with Lexapro and for which the incidence in patients treated with Lexapro was greater than the incidence in placebo-treated patients. The prescriber should be aware that res can not be used to predict the incidence of adverse events in the course of usual medical practice where patient characteristics and other factors differ from those which prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different s, uses, and investigators. The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contribution of drug and non-drug factors to the adverse event incidence rate in the population studied. The most commonly observed adverse events in Lexapro patients (incidence of approxi- % or greater and approximately twice the incidence in placebo patients) were insomnia, ejaculation disorder (primarily ejaculatory delay), nausea, sweating increased, fatigue, and somnolence (see **TABLE 1**). **TABLE 1: Treatment-Emergent Adverse Events: Incidence in Placebo-Controlled Clinical Trials for Major Depressive * [Lexapro (N=715) and Placebo (N=592)]: Autonomic Nervous System Disorders:** Dry Mouth (6% and 5%); Sweating Increased (5% and 2%). **Central & Peripheral Nervous System Disorders:** Dizziness (5% and 3%). **Gastrointestinal Disorders:** Nausea (15% and 7%); Diarrhea (8% and 5%); Constipation (3% and 1%); n (3% and 1%); Abdominal Pain (2% and 1%). **General:** Influenza-like Symptoms (5% and 4%); Fatigue (5% and 2%). **Psychiatric Disorders:** Insomnia (9% and 4%); Somnolence (6% and 2%); Appetite Decreased (3% and 1 %); Libido Decreased (3% and 1%). **Respiratory System Disorders:** Rhinitis (5% and 4%); Sinusitis 2%). **Urogenital:** Ejaculation Disorder[1,2] (9% and <1%); Impotence[2] (3% and <1%); Anorgasmia[3] (2% and <1%). *Events reported by at least 2% of patients treated with Lexapro are reported, except for the following events which had an incidence on placebo ≥ Lexapro: headache, upper respiratory tract infection, back pain, pharyn- cted injury, anxiety. [1]Primarily ejaculatory delay. [2]Denominator used was for males only (N=225 Lexapro; N=188 placebo). [3]Denominator used was for females only (N=490 Lexapro; N=404 placebo). **Generalized Anxiety Disorder** Table 2 enumerates the incidence, rounded to the nearest percent of treatment-emergent adverse at occurred among 429 GAD patients who received Lexapro 10 to 20 mg/day in placebo-controlled trials. Events included are those occurring in 2% or more of patients treated with Lexapro and for which the incidence in patients treated with Lexapro was greater than the incidence in placebo-treated patients. The most common- ed adverse events in Lexapro patients (incidence of approximately 5% or greater and approximately twice the incidence in placebo patients) were nausea, ejaculation disorder (primarily ejaculatory delay), insomnia, fatigue, decreased libido, and anorgasmia (see **TABLE 2**). **TABLE 2: Treatment-Emergent Adverse Events: Incidence o-Controlled Clinical Trials for Generalized Anxiety Disorder* [Lexapro (N=429) and Placebo (N=427)]: Autonomic Nervous System Disorders:** Dry Mouth (9% and 5%); Sweating Increased (4% and 1%). **Central & Peripheral Nervous System Disorders:** Headache (24% and 17%); Paresthesia (2% and 1%). **Gastrointestinal s:** Nausea (18% and 8%); Diarrhea (8% and 6%); Constipation (5% and 4%); Indigestion (3% and 2%); Vomiting (3% and 1%); Abdominal Pain (2% and 1%); Flatulence (2% and 1%); Toothache (2% and 0%). **General:** Fatigue (8% and 2%); Influenza-like symptoms (5% and 4%). **Musculoskeletal:** Neck/Shoulder Pain (3% **Psychiatric Disorders:** Somnolence (13% and 7%); Insomnia (12% and 6%); Libido Decreased (7% and 2%); Dreaming Abnormal (3% and 2%); Appetite Decreased (3% and 1%); Lethargy (3% and 1%); Yawning (2% and 1%). **Urogenital:** Ejaculation Disorder[1,2] (14% and 2%); Anorgasmia[3] (6% and <1%); Menstrual Disorder 1%). *Events reported by at least 2% of patients treated with Lexapro are reported, except for the following events which had an incidence on placebo Lexapro: inflicted injury, dizziness, back pain, upper respiratory tract infection, rhinitis, pharyngitis. [1]Primarily ejaculatory delay. [2]Denominator used was for males only (N=182 N=195 placebo). [3]Denominator used was for females only (N=247 Lexapro; N=232 placebo). **Dose Dependency of Adverse Events** The potential dose dependency of common adverse events (defined as an incidence rate of ≥5% in either the 10 mg or 20 mg Lexapro groups) was examined on the basis of the combined incidence e events in two fixed-dose trials. The overall incidence rates of adverse events in 10 mg Lexapro-treated patients (66%) was similar to that of the placebo-treated patients (61%), while the incidence rate in 20 mg/day Lexapro-treated patients was greater (86%). Table 3 shows common adverse events that occurred in the 20 mg/day group with an incidence that was approximately twice that of the 10 mg/day Lexapro group and approximately twice that of the placebo group. **TABLE 3: Incidence of Common Adverse Events* in Patients with Major Depressive Disorder Receiving Placebo (N=311), 10 mg/day Lexapro (N=310), 20 mg/day Lexapro (N=125)]: (4%, 7%, 14%); Diarrhea (5%, 6%, 14%); Dry Mouth (3%, 4%, 9%); Somnolence (1%, 4%, 9%); Dizziness (2%, 4%, 7%); Sweating Increased (<1%, 3%, 8%); Constipation (1%, 3%, 6%); Fatigue (2%, 2%, 6%); Indigestion (1%, 2%, 6%).** *Adverse events with an incidence rate of at least 5% in either of the Lexapro groups an incidence rate in the 20 mg/day Lexapro group that was approximately twice that of the 10 mg/day Lexapro group and the placebo group. **Male and Female Sexual Dysfunction with SSRIs** Although changes in sexual desire, sexual performance, and sexual satisfaction often occur as manifestations of a psychiatric disorder, also be a consequence of pharmacologic treatment. In particular, some evidence suggests that SSRIs can cause such untoward sexual experiences. Reliable estimates of the incidence and severity of untoward experiences involving sexual desire, performance, and satisfaction are difficult to obtain, however, in part because patients icians may be reluctant to discuss them. Accordingly, estimates of the incidence of untoward sexual experience and performance cited in product labeling are likely to underestimate their actual incidence. Table 4 shows the incidence rates of sexual side effects in patients with major depressive disorder and GAD in placebo-con- ials. **TABLE 4: Incidence of Sexual Side Effects in Placebo-Controlled Clinical Trials [In Males Only: Lexapro** (N=407) **and Placebo** (N=383)]: Ejaculation Disorder (primarily ejaculatory delay) (12% and 1%); Libido Decreased (6% and 2%); Impotence (2% and <1%). [In Females Only: **Lexapro** (N=737) **and Placebo** (N=636)]: ecreased (3% and 1%); Anorgasmia (3% and <1%) There are no adequately designed studies examining sexual dysfunction with escitalopram treatment. Priapism has been reported with all SSRIs. While it is difficult to know the precise risk of sexual dysfunction associated with the use of SSRIs, physicians should routinely inquire ch possible side effects. **Vital Sign Changes** Lexapro and placebo groups were compared with respect to (1) mean change from baseline in vital signs (pulse, systolic blood pressure, and diastolic blood pressure) and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these . These analyses did not reveal any clinically important changes in vital signs associated with Lexapro treatment. In addition, a comparison of supine and standing vital sign measures in subjects receiving Lexapro indicated that Lexapro treatment is not associated with orthostatic changes. **Weight Changes** Patients treated with in controlled trials did not differ from placebo-treated patients with regard to clinically important change in body weight. **Laboratory Changes** Lexapro and placebo groups were compared with respect to (1) mean change from baseline in various serum chemistry, hematology, and urinalysis variables, and (2) the incidence of patients criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed no clinically important changes in laboratory test parameters associated with Lexapro treatment. **ECG Changes** Electrocardiograms from Lexapro (N=625), racemic citalopram (N=351), and placebo (N=527) groups were d with respect to (1) mean change from baseline in various ECG parameters and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed (1) a decrease in heart rate of 2.2 bpm for Lexapro and 2.7 bpm for racemic citalopram, compared to se of 0.3 bpm for placebo and (2) an increase in QTc interval of 3.9 msec for Lexapro and 3.7 msec for racemic citalopram, compared to 0.5 msec for placebo. Neither Lexapro nor racemic citalopram were associated with the development of clinically significant ECG abnormalities. **Other Events Observed During the Premarketing on of Lexapro** Following is a list of WHO terms that reflect treatment-emergent adverse events, as defined in the introduction to the **ADVERSE REACTIONS** section, reported by the 1428 patients treated with Lexapro for periods of up to one year in double-blind or open-label clinical trials during its premarketing evaluation. All report- s are included except those already listed in Tables 1 & 2, those occurring in only one patient, event terms that are so general as to be uninformative, and those that are unlikely to be drug related. It is important to emphasize that, although the events reported occurred during treatment with Lexapro, they were not necessarily caused ents are further categorized by body system and listed in order of decreasing frequency according to the following definitions: frequent adverse events are those occurring on one or more occasions in at least 1/100 patients; infrequent adverse events are those occurring in less than 1/100 patients but at least 1/1000 patients. scular - *Frequent:* palpitation, hypertension. *Infrequent:* bradycardia, tachycardia, ECG abnormal, flushing, varicose vein. Central and Peripheral Nervous System Disorders - *Frequent:* light-headed feeling, migraine. *Infrequent:* tremor, vertigo, restless legs, shaking, twitching, dysequilibrium, tics, carpal tunnel syndrome, muscle con- involuntary, sluggishness, coordination abnormal, faintness, hyperreflexia, muscular tone increased. Gastrointestinal Disorders - *Frequent:* heartburn, abdominal cramp, gastroenteritis. *Infrequent:* gastroesophageal reflux, bloating, abdominal discomfort, dyspepsia, increased stool frequency, belching, gastritis, hemorrhoids, gag- lyposis gastric, swallowing difficult. General - *Frequent:* allergy, pain in limb, fever, hot flushes, chest pain. *Infrequent:* edema of extremities, chills, tightness of chest, leg pain, asthenia, syncope, malaise, anaphylaxis, fall. Hemic and Lymphatic Disorders - *Infrequent:* bruise, anemia, nosebleed, hematoma, lymphadenopathy cervi- abolic and Nutritional Disorders - *Frequent:* increased weight. *Infrequent:* decreased weight, hyperglycemia, thirst, bilirubin increased, hepatic enzymes increased, gout, hypercholesterolemia. Musculoskeletal System Disorders - *Frequent:* arthralgia, myalgia. *Infrequent:* jaw stiffness, muscle cramp, muscle stiffness, arthritis, mus- ness, back discomfort, arthropathy, jaw pain, joint stiffness. Psychiatric Disorders - *Frequent:* appetite increased, lethargy, irritability, concentration impaired. *Infrequent:* jitteriness, panic reaction, agitation, apathy, forgetfulness, depression aggravated, nervousness, restlessness aggravated, suicide attempt, amnesia, anxiety attack, carbohydrate craving, confusion, depersonalization, disorientation, emotional lability, feeling unreal, tremulousness nervous, crying abnormal, depression, excitability, auditory hallucination, suicidal tendency. Reproductive Disorders/Female* - *Frequent:* menstrual cramps, menstrual disorder. *Infrequent:* menorrhagia, breast neo- elvic inflammation, premenstrual syndrome, spotting between menses. *% based on female subjects only: N= 905 Respiratory System Disorders - *Frequent:* bronchitis, sinus congestion, coughing, nasal congestion, sinus headache. *Infrequent:* asthma, breath shortness, laryngitis, pneumonia, tracheitis. Skin and Appendages s - *Frequent:* rash. *Infrequent:* pruritus, acne, alopecia, eczema, dermatitis, dry skin, folliculitis, lipoma, furunculosis, dry lips, skin nodule. Special Senses - *Frequent:* vision blurred, tinnitus. *Infrequent:* taste alteration, earache, conjunctivitis, vision abnormal, dry eyes, eye irritation, visual disturbance, eye infection, pupils dilated, taste. Urinary System Disorders - *Frequent:* urinary frequency, urinary tract infection. *Infrequent:* urinary urgency, kidney stone, dysuria, blood in urine. Events Reported Subsequent to the Marketing of Escitalopram - Although no causal relationship to escitalopram treatment has been found, the following adverse events have been l to have occurred in patients and to be temporally associated with escitalopram treatment during post marketing experience and were not observed during the premarketing evaluation of escitalopram: abnormal gait, acute renal failure, aggression, akathisia, allergic reaction, anger, angioedema, atrial fibrillation, choreoathetosis, delusion, diplopia, dysarthria, dyskinesia, dystonia, ecchymosis, erythema multiforme, extrapyramidal disorders, fulminant hepatitis, hepatic failure, hypoaesthesia, hypoglycemia, hypokalemia, INR increased, gastrointestinal hemorrhage, glaucoma, grand mal seizures (or convulsions), hemolytic anemia, hepatic necrosis, hepati- tension, leucopenia, myocardial infarction, myoclonus, neuroleptic malignant syndrome, nightmare, nystagmus, orthostatic hypotension, pancreatitis, paranoia, photosensitivity reaction, priapism, prolactinemia, prothrombin decreased, pulmonary embolism, QT prolongation, rhabdomyolysis, seizures, serotonin syndrome, SIADH, eous abortion, Stevens Johnson Syndrome, tardive dyskinesia, thrombocytopenia, thrombosis, torsade de pointes, toxic epidermal necrolysis, ventricular arrhythmia, ventricular tachycardia and visual hallucinations.

d from H. Lundbeck A/S

Rev. 09/06

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February 14, 2007

Deborah Platt Majoras, Chairman
FTC
6th & Pennsylvania Avenue
Washington, DC 20580

Steve Galson, M.D., MPH
Director, CDER
FDA, 5515 Security Lane
Rockville, MD 20857

RE: DIRECT-TO-CONSUMER ADVERTISING
PRINT SIZE READABILITY

Dear Ms. Majoras and Dr. Galson:

Pharmacists Planning Service, Inc. (PPSI) is a 501 C (3) nonprofit public health, consumer, pharmacy education organization is greatly concerned about the direct-to-consumer (DTC) print size readability and the ability for patients and consumers who read these ads to understand them. These ads basically are for prescription drugs and in many cases are promoting the prescription drugs but patients and consumers are not able to read them.

I am sending you a series of advertisements from various magazines. Please note the difficulty patients and consumers have in reading them, especially seniors, who are only 13% of the population but use 43% of all prescription drugs, over-the-counter (OTC) drugs and herbals.

In 1990 PPSI petitioned FDA on label readability guidelines and introduced legislation in California to increase the print size for patients and consumers to improve the readability on nonprescription medicine labels. California Assembly Bill 2713 was signed into law by the Governor and was enacted regarding print size on OTCs. In October, 1990 the Nonprescription Drug Manufacturers Association (NDMA) put out label readability guidelines after two years of study from a task force entitled "Draft Guidelines for Maximizing Label Readability". I am enclosing a copy of the Label Readability Guidelines by NDMA.

PPSI requests that FTC and FDA get uniformity and guidelines for readability for direct-to-consumer advertising so that patients and consumers, especially seniors, are able to read prescription drug advertisements.

Under separate cover, I would like to submit a Citizen's Petition regarding direct-to-consumer (DTC) advertising and print and label readability in the current advertising of prescription drugs, over-the-counter (OTC) drugs, herbals and alternative medicines, etc.

Sincerely,

Fred S. Mayer, R.Ph., M.P.H.
President

Enclosures

30

Tuesday, November 7: 2:30 PM-4:00 PM
Room 54 Boston Convention Center

A Panel Discussion

Drug Manufacturers, the FDA, and U.S. Health Care:

How Can the Public Be Assured of Access to Safe, Effective Medicines?

The past decade has brought increasingly sharp criticism of the drug industry by both health professionals and the general public. The industry is widely seen not only as promoting development of groundbreaking new therapies but also as wielding its economic power to exert undue, self-serving influence over scientific, legislative, and regulatory processes; training of professionals; and information flow among scientists, health professionals and the public. Further, it is seen as abusing the patent system to price medicines beyond the reach of many who need them while straining government finances as well.

The panel will examine these criticisms and discuss the need for reforms.
Each panel member will make a three-minute opening statement.
The moderator will then pose questions, with panelists offering one-minute responses.
Audience participation will follow.

Panel:*

John D. Abramson – Harvard Medical School; author, "Overdosed America"

Marcia Angell – Harvard Medical School; author, "The Truth About the Drug Companies"

David J. Graham – FDA Office of Surveillance & Epidemiol.; recipient, APHA Award for Excellence

Jerome P. Kassirer – Tufts U. School of Medicine; author, "On the Take"

Deborah Socolar – Boston U. School of Public Health; Director, BUSPH Health Reform Program

Moderator:

Merrill Goozner – Center for Science in the Public Interest; Dir., CSPI Integrity in Science Project

* Listed participants will speak on their own behalf, not as representing their institutions or agencies.

5 widely used drugs called unsafe

FDA officer says conflicts of interest compromise agency

By Marc Kaufman
WASHINGTON POST

WASHINGTON — A veteran ood and Drug Administration afety officer Thursday told a Sente hearing inquiring into the brupt recall of the arthritis drug ioxx that five other widely used rugs should be either withdrawn r sharply restricted because they ave dangerous side effects.

Describing the agency that he orks for as incapable of stopping dangerous rugs from coming to and staying on the market, David Graham, associate rector of the ffice of Drug afety, told the nators that the DA's role in reewing and approving new drugs metimes conflicted with its duty address safety issues.

David Graham

Asked by Sen. Jeff Bingaman, D-M., to identify the five drugs, raham hesitated and then listed em to the startled hearing room: e popular cholesterol-lowering ug Crestor, the weight-loss drug eridia, the painkiller Bextra, the ne medication Accutane and the hma medication Serevent.

Each poses different issues, Graham said in answer to questions om senators, but all require more gressive action by the FDA.

AstraZeneca's Crestor, he said, oses risks of kidney failure and a ue muscle disease; Abbott Laboratories Inc.'s Meridia is of little use id has cardiovascular side effects; oche's Accutane can cause birth fects if used by pregnant women; izer's Bextra carries cardiovascu- risks similar to those linked to oxx; and GlaxoSmithKline's Sevent increases the risk of dying of hma. The makers of all five igs later defended their products orously.

Dr. Steven Galson, acting director of the FDA's Center for Drug Evaluation and Research, said the agency already had taken steps to alert consumers to those drugs' safety concerns. That includes heightened warnings for Serevent; a tougher risk-management plan to ensure pregnant women don't use Accutane, and an upcoming advisory committee hearing regarding Bextra.

A 20-year veteran of the FDA, Graham has played a significant role in the withdrawal of nine drugs over the past decade, and his highly unusual attack on his own agency astonished many in the room. He called the FDA's handling of Merck & Co.'s Vioxx — which he said should have been pulled from the market years ago — the most distressing episode of all and a "profound regulatory failure."

"I would argue that the FDA as currently configured is incapable of protecting America against another Vioxx," Graham said in his scathing assessment. "The scientific standards (the FDA) applies to drug safety guarantee that unsafe and deadly drugs will remain on the U.S. market."

Citing estimates he said were based on the results of Merck's own clinical trials, Graham said between 88,000 and 139,000 Americans had probably had heart attacks or strokes as a result of taking Vioxx, and that 30 to 40 percent had probably died.

Graham also contended that FDA had an inherent conflict of interest that triggered "denial, rejection and heat" when safety questions emerged about products it had approved.

Graham's sentiments were endorsed at the hearing by two other drug safety experts, but they were disputed by a ranking FDA official as "not the FDA that I know."

Sandra Kweder, deputy director of the Office of New Drugs, said the agency was dedicated to protecting consumers and that drug safety was at the heart of its activities. She acknowledged, however, that "clearly, there's concern by the public and this committee that the system isn't working as well as it should, and we need to address that."

Asked about the five drugs that Graham identified as needing immediate action, Kweder said, "I don't have reason to believe that set of five drugs gives more reason for concern than any other set."

Graham's revelations and criticisms were the centerpiece of the hearing called by Sen. Charles Grassley, R-Iowa, chairman of the Senate Finance Committee and an increasingly sharp critic of the FDA. Following Graham's comments, Grassley pointedly warned agency officials against disciplining Graham in any way.

Grassley also suggested that an independent board of drug safety may be needed to ensure the safety of medications after FDA approval. An "awful lot of red flags" were raised before Vioxx was withdrawn, said Grassley, and the agency disdained, rather than listened to, its own reviewers.

Merck CEO Raymond Gilmartin came to the defense of the FDA and his company's actions in dealing with the issues around Vioxx, a heavily advertised and hugely profitable drug until it was abruptly recalled in September. He said the company had no scientific reason to withdraw the drug until it heard clear negative results reported by the safety monitoring committee of a clinical trial. At the time, Gilmartin said, his own wife was regularly taking the drug.

"Throughout Merck's history, it has been our rigorous adherence to scientific investigation, openness and integrity that has enabled us to bring new medicines to people who need them," Gilmartin said. "I am proud that we followed that same rigorous scientific process at every step of the way with Vioxx."

One of a class of painkillers known as COX-2 inhibitors that are widely used by arthritis sufferers, Vioxx was introduced in 1999. It was withdrawn after researchers halted a clinical trial because patients taking Vioxx were experiencing twice as many heart attacks and strokes as patients taking a placebo, but witnesses testified there had been suggestions of possible cardiovascular risks going back the mid-1990s.

Officials of the companies whose drugs were cited by Graham all said they were surprised by his testimony.

Carolyn Glynn, a spokeswoman for Roche, said it had long recognized that Accutane required special handling because of its known connection to birth defects.

AstraZeneca, the maker of Crestor, said in a statement that "to date, the FDA has not given the company any indication of a major concern regarding Crestor, and the comments today are inconsistent with past public statements from the FDA."

Abbott Laboratories issued a statement defending its weight-loss drug Meridia. "Obesity remains one of the leading health epidemics in the U.S., and Meridia is one of the few effective drugs that are currently available," it said.

GlaxoSmithKline stood by its asthma drug Serevent, saying it was "safe and effective when used appropriately."

Pfizer spokeswoman Susan Bro said its Cox-2 drug, Bextra, "has been found safe and effective when used as indicated." She noted that the company had already "committed to conducting further studies to confirm the longer-term cardiovascular safety profile."

The Associated Press contributed to this report.

Worrisome drugs?

Five drugs cited by a Food and Drug Administration official as the worst examples of those that remain on the market despite safety concerns:

- **Accutane**, a treatment for severe acne linked to birth defects and fetal death when used by pregnant women.
- **Bextra**, a painkiller found in a recent study to more than double the risk of heart attacks and strokes among patients with heart disease.
- **Crestor**, an anti-cholesterol drug linked to a muscle-destroying side effect and acute renal failure.
- **Meridia**, an obesity treatment linked to heart problems and, among pregnant women, stillbirths, miscarriages and birth defects.
- **Serevent**, an asthma medication that a study in England linked to increased deaths.

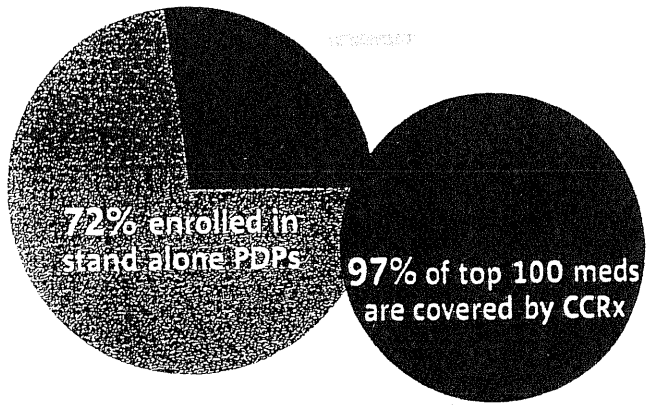
Source: Associated Press

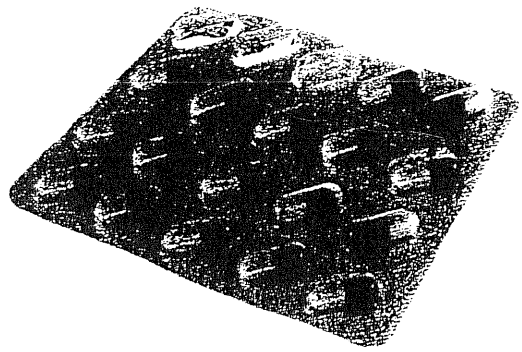
NOTE - ENCLOSED !! 18

You Are in Good Company.

More than 72% of Medicare beneficiaries with Part D coverage are enrolled in stand-alone Prescription Drug Programs like CCRx, while 18% are enrolled in Medicare Advantage Prescription Drug Plans, according to an Avalere Health analysis of Centers for Medicare & Medicaid Services (CMS) data.

The CCRx drug list (formulary) covers 97% of the top 100 medications taken by Medicare beneficiaries. This percentage applies to medications allowed under Part D.





MemberHealth #1

Of the top 20 preferred brand medications most often prescribed to seniors, CCRx covers more than any other Part D provider—17 out of 20 medications are on our preferred drug list.

Source: Procter & Gamble Pharmaceuticals Research analysis of data from the Centers for Medicare and Medicaid Services

New Additions to the CCRx List of Covered Drugs

Medication	Tier	Common Uses
finasteride (generic Proscar®)	Generic	Enlarged prostate
simvastatin (generic Zocor®)	Generic	High cholesterol
meloxicam	Generic	Pain, Arthritis
Levemir®	Preferred Brand	Diabetes
Azilect®	Brand	Parkinson's disease
Innohep®	Brand	Blood clots
Lacrisert®	Brand	Severe dry eyes
Sanctura®	Brand	Overactive bladder
Tygacil®	Brand	Infections (antibiotic)
Other Changes to the CCRx Formulary		
Crestor® — Now a preferred brand medication	Preferred Brand	High cholesterol

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Support CMS efforts to make Part D data available for research

CMS is soliciting comments on the proposed rule for collection of Part D (Medicare drugs) data for evaluation and research.

If you wish to support this, comments are due by *12/18/06*. The full text appears in the Federal Register, vol. 71, no. 201, 10/18/06, pages 61445-61455.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 423

[CMS–4119–P]

RIN # 0938–AO58

Medicare Program; Medicare Part D Data

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would allow the Secretary to use the claims information that is now being collected for Part D payment purposes for other research, analysis, reporting, and public health functions. The Secretary needs to use this data because other publicly available data are not, in and of themselves, sufficient for the studies and operations that the Secretary needs to undertake as part of the Department of Health and Human Service's obligation to oversee the Medicare program, protect the public health, and respond to Congressional mandates.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 18, 2006.

ADDRESSES: In commenting, please refer to file code CMS–4119–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* Click on the link "Submit electronic comments on CMS regulations with an open comment period." (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address *only:* Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4119–P, P.O. Box 8017, Baltimore, MD 21244–8017.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address *only:* Centers for Medicare &

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Practitioner-Managed Prescription Drug Plan (PMPDP)
All drugs listed below were evaluated by the Health Resources Commission (HRC) using an evidence-based review process. HRC identified drugs of similar or superior benefit when used as the initial treatment for the majority of patients. DHS limited the list of identified drugs to the most cost effective. Therapeutic prior authorization (PA) requirements still apply to drugs listed in the PDL classes (OAR 410-21-0040).

Plan Drug List (PDL)
Note: (**) This drug represents the benchmark drug for the class.

ALZHEIMER'S DRUGS:
(**)Aricept
- Exelon
- Namenda
- Razadyne

ANGIOTENSIN-CONVERTING ENZYME (ACE) INHIBITORS:
- (**)Enalapril (generic)
- Aceon
- Captopril (generic)
- Lisinopril (generic)
- Uniretic

ANGIOTENSIN II RECEPTOR ANTAGONISTS (AIIRA):
- (**)Cozaar
- Avalide
- Avapro
- Atacand
- Atacand HCT
- Benicar
- Benicar HCT
- Diovan
- Diovan HCT
- Hyzaar
- Micardis
- Micardis HCT
- Tevetin
- Tevetin HCT

BETA-BLOCKERS:
- (**)Toprol XL
- Acebutolol (generic)
- Atenolol (generic)
- Bisoprolol (generic)
- Inderal LA
- Innopran XL
- Labetolol (generic)
- Metoprolol tartrate (generic)
- Nadolol (generic)
- Pindolol (generic)
- Propranolol (generic)
- Timolol (generic)

CALCIUM CHANNEL BLOCKERS:
Dihydropyridines:
- (**) Norvasc
- Nicardipine (generic)
- Nifedipine (generic)
- Nifedipine CC tablets (AB generics for Adalat CC)
- Nifedipine XL tablets (AB generics for Procardia XL)
- Sular

Non-Dihydropyridines:
- (**)Verapamil Sustained Action tablets (AB generic for Isoptin SR)
- Diltiazem IR (generic)
- Verapamil IR (generic)

ESTROGENS:
Oral Products
- (**) Estradiol (generic)
- Menest

Transdermal Products
- (**) Estradiol patch (generic)
- Alora

- Estraderm
- Vivelle

ESTROGENS, cont.
Vaginal Products
- (**) Vagifem
- Premarin

HYPOGLYCEMICS, ORAL:
- (**) Glyburide (generic)
- Glipizide (generic)

INHALED CORTICOSTEROIDS:
- (**) QVAR
- Flovent
- Aerobid, Aerobid-M

NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAID):
- (**) Naproxen (generic)
- Ibuprofen (generic)
- Indomethacin (generic)
- Piroxicam (generic)

OPIOIDS, LONG-ACTING:
- (**) LA-Morphine Sulfate (generic)
- Levorphanol (generic)
- Kadian
- Methadone HCL (generic)
- Oramorph SR

PROTON PUMP INHIBITORS:
- (**)Prilosec OTC

SKELETAL MUSCLE RELAXANTS
Antispasmodics for chronic neurological conditions:
- (**) Baclofen (generic)

Acute/chronic musculoskeletal spasms:
- (**)Cyclobenzaprine (generic)

STATINS (CHOLESTEROL-LOWERING MEDICATIONS):
Low/Medium Potency
- (**) Lovastatin (generic)
- Altoprev
- Lescol
- Lescol XL
- Pravachol

High Potency
- Lipitor
- Zocor

TRIPTAN DRUGS:
- (**) Maxalt
- Amerge
- Axert
- Imitrex
- Maxalt MLT
- Relpax
- Zomig
- Zomig ZMT

Nasal
(**) Zomig
- Imitrex

Subcutaneous
(**) Imitrex

OVERACTIVE BLADDER DRUGS:
- (**) Oxybutynin (tablets and liquid)

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Risks from popular medications detailed

Bad drug reactions send 700,000 to ER yearly, study says

By Lindsey Tanner
Associated Press

CHICAGO — Harmful reactions to some of the most widely used medicines — from insulin to a common antibiotic — sent more than 700,000 Americans to emergency rooms each year, landmark government research shows.

Accidental overdoses and allergic reactions to prescription drugs were the most frequent cause of serious illnesses, according to the study, the first to reveal the nationwide scope of the problem. People over 65 faced the greatest risks.

"This is an important study because it reinforces the really substantial risks that there are in everyday use of drugs," said patient safety specialist Bruce Lambert, a professor at the University of Illinois at Chicago's college of pharmacy.

Even so, the study authors and other experts agreed that the 700,000 estimate was conservative because bad drug reactions are likely often misdiagnosed.

The study found that a small group of pharmaceutical warhorses were most commonly implicated, including insulin for diabetes; warfarin for clotting problems; and amoxicillin, a penicillin-like antibiotic used for all kinds of infections.

"These are old drugs which are known to be extremely effective. We could not and would not want to live without them. But you've got to get the dose exactly right. Variations, especially on the high side, are really dangerous," Lambert said. He was not involved in the research.

See Drugs, page A11

From page A1

Those aged 65 and older faced more than double the risk of requiring emergency room treatment and were nearly seven times more likely to be admitted to the hospital than younger patients.

The results, from 2004-05, represent the first two years of data from a national surveillance project on outpatient drug safety. The project was developed by the federal Centers for Disease Control and Prevention, the Food and Drug Administration and the U.S. Consumer Product Safety Commission. The study was published in today's Journal of the American Medical Association.

The database included 63 nationally representative hospitals that reported 21,298 bad drug reactions among U.S. adults and children treated in emergency rooms during the two-year period. The tally is based on what emergency room doctors said were complications from using prescription drugs, over-the-counter medicines, dietary supplements or herbal treatments.

The researchers said it translates to 701,547 complications nationwide each year.

"Experts had thought that severe outpatient drug events were common, but no one really had good numbers" until now, said lead author Dr. Daniel Budnitz, a CDC researcher.

Complications included diabetics on insulin passing out from low-blood sugar, excessive bleeding in patients on warfarin and severe skin rashes in patients taking amoxicillin. Drug reactions were severe enough to require hospitalization in about 17 percent of patients. The study did not include information on whether any of the reactions were fatal.

"The numbers are quite troubling," said Jim Conway, senior vice president at the Institute for Healthcare Improvement. The tally underscores that "there is a tremendous number of consumers in the United States taking medication."

The CDC has estimated that about 130 million Americans use prescribed medication every month. U.S. consumers buy far more medicine per person than anywhere else in the world.

AVOIDING BAD DRUG REACTIONS

Here are some ways to avoid bad reactions to common medications:

- When a physician prescribes a new medicine, don't leave the doctor's office without knowing the correct dose, how often to take it, possible side effects or symptoms of allergy or overdose, and what to do if those symptoms occur.
- Ask if there are foods, drinks, other medicines, or activities that should be avoided while taking the drug.
- Ask if you'll need periodic blood tests or other monitoring to make sure the drug is working properly.
- Ask your doctor similar questions about any over-the-counter medicines, dietary supplements or herbal products you use, and if they might have bad interactions with prescription drugs.
- Notify your doctor about any significant weight gain or loss or change in diet or activity level that might require changing the dose of a prescription drug.
- Don't stop taking a prescribed drug without notifying your doctor.

Sources include Agency for Healthcare Research and Quality and patient safety experts.

Yet a recent study found that doctors' conversations with patients when prescribing new drugs aren't very thorough and that side effects often aren't mentioned. Many of the drugs implicated in the new study require frequent physician monitoring to make sure the dose is correct.

The new findings highlight the need for better doctor-patient communication about use of medicines, Conway said.

The number likely underestimates the number of people who have bad drug reactions outside a hospital setting because many don't get ER treatment, while others who do may have symptoms that are mistakenly attributed to something else, said patient safety expert Dr. David Bates, a professor at Harvard Medical School.

NACDS
NATIONAL ASSOCIATION OF CHAIN DRUG STORES FOUNDATION

The Practice Memo

VOLUME 10 | NUMBER 11 | NOVEMBER 2006

KEY PRACTICE AND OPERATIONAL ISSUES FOR TODAY'S COMMUNITY PHARMACIST

It's time to talk about Value!

Proving the value of pharmacy and prescription medications

For many decades, community pharmacists and prescription medications have been integral components of health care in this country. And although the services provided by pharmacists and the benefits received by prescription medications continue to grow in importance, the public does not always perceive these benefits as valuable components of their health care.

Community pharmacists, on the other hand, are well aware of the value they bring to the health care system, as well as the value of taking prescription medications properly. To help pharmacists prove the value of community pharmacy and prescription medications to their patients, we've devoted this themed issue of The Practice Memo to spreading the "value message" -- a message that communicates the value of the community pharmacist and prescription medication so that the public is more aware of the vast benefits they receive every time they visit a pharmacy.

Throughout this issue, take note of the red "call-to-action" boxes ☐ which help provide pharmacists and technicians with simple ideas for helping communicate and demonstrate value to patients.

By demonstrating value, pharmacists can improve health and decrease overall health care costs

In today's community pharmacy, most patients have two primary concerns -- *cost* and *convenience*. While these are understandable concerns, often times this thought process results in patients treating their prescriptions and their experience at the pharmacy counter as "commodities." This equates to patients placing little value on these important and critical components of their health care, and often puts them at risk for suboptimal medication therapy (see box right).

Lack of value leads to:

- Inappropriate use of medication
- Increased adverse effects
- Decreased adherence
- Increased overall health care costs

As medication experts and the most accessible health care professional, community pharmacists are in an ideal position to help patients better understand their medications as well as maximize the benefits from those medications.

Why NOW is the time to spread the value message

Unless the public, which includes insurance plans, pharmacy benefit managers (PBMs), legislators, and patients, begins to understand the value that pharmacists bring to health care, the challenges and threats for community pharmacy will expand:

- Medicaid/PBM reimbursement cuts will continue.
- Mail order competition will grow.
- Pharmacists will become insurance experts instead of medication experts.
- Other health care practitioners will provide Medication Therapy Management (MTM) services instead of community pharmacists.

Role of the pharmacist in spreading the value message: Tell your patients what you do for them

Although pharmacists have been ranked among the top professionals in trustworthiness by consumers for decades, unfortunately patients do not always equate this with value of services. One of the main reasons is that patients are unaware of what pharmacists do for them. While they know pharmacists provide them with the right medication and bill their insurance, many are unaware that pharmacists check for dangerous drug interactions, verify appropriate dosing, offer free counseling services, and much, much more.

> ***Tell your patients what you do***
>
> Be proactive. Simply letting patients know what you do and how you maximize their health outcomes can help patients better value your services.

On top of that, many still don't view pharmacists as health care providers, and have no idea that pharmacists go through a minimum of six years of specialized training -- or that they provide immunizations, health screenings, medication therapy management (MTM), and other valuable health care services.

> ***Use "Why does it take so long to fill my prescription?" as an opportunity***
>
> Although most pharmacists and technicians cringe when they hear "Why does it take so long to fill my prescription?" from their patients, this can be used as an opportunity to demonstrate value. When patients ask this question, be sure to tell them all of the valuable services you provide with each prescription. For more help with identifying value opportunities for both pharmacists and technicians, visit *www.pharmacyvaluealliance.org* and click on "CE/Training Tools."

Shifting the focus of prescription medication from cost to value

There's no question that some prescription medications can be expensive. Monthly co-pays continue to grow and the development of newer, innovative therapies often equates to patients taking more prescription medications, thus increasing their out-of-pocket costs.

Yet, patients rarely stop to think about the value they receive from their prescription medications. They often forget that taking medication keeps them healthy, at work, out of the hospital, away from their doctor's office -- and usually prevents them from spending more money on other health care services.

Money well spent

- For every $1 spent on prescription medication, there is a $4 decrease in hospital costs.
- For every $1 spent on ACE inhibitors, there is a $6 decrease in hospital costs in CHF patients.
- For every $3 spent on asthma medication, there is a $17 decrease in emergency room spending.

The truth is that some prescription medications may be expensive -- but if patients think about what they get out of those medications, they'll see that it is *money well spent.* Pharmacists can help patients shift their focus from cost to value so that they better understand what they're paying for.

> ***Help patients afford their prescriptions with PPA***
>
> If patients are having trouble affording their prescription medications, recommend they visit *www.pparx.org* or call 1-888-4PPA-NOW. The Partnership for Prescription Assistance (PPA) helps patients identify and enroll in one of nearly 500 private or public patient assistance programs.

Medication Therapy Management by pharmacists can help prove value, limit health care spending, and improve health outcomes

The inclusion of Medication Therapy Management (MTM) in the Medicare Modernization Act (MMA) presents community pharmacists with a great opportunity to help prove their value in today's health care system. Representing the first time that pharmacists nationwide are being recognized and paid for providing a service, MTM opens the door for community pharmacy to help patients better manage their medications and reduce overall health care spending.

The need for MTM could not be higher

While the public continues to focus on the cost of medication as a cause of increased health care costs in the U.S., one area where we need to start looking is the cost of mis-management of medications -- as this amount actually exceeds the amount spent on the medication itself (see box right).

In 2000 the U.S. spent:

$144 Billion on prescription medications
AND
$177 Billion on medication-related problems

Further emphasizing the need for better management of medications, adherence rates in the U.S. remain significantly low for many common disease states:

- Blood pressure: 51%
- Depression: 40-70%
- HIV: 37-83%
- Acute asthma: 43%
- Chronic asthma: 28%

It all leads to value and opportunity for community pharmacy!

By looking at these statistics, it's evident that the public does not value their medications, nor do they understand the value of the community pharmacist in helping maximize the benefits of and limit the problems associated with medications. And while the lack of value is apparent, at the same time, community pharmacy has the best opportunity to make a difference -- by providing effective MTM services which improve adherence, limit adverse effects, and keep patients healthy with their valuable medications.

Just a glimpse at a sample of 100 prescriptions (see box right) provides pharmacists with a variety of opportunities to help improve health care.

Opportunities to improve medication therapy*

Out of **100 written prescriptions**:

- **50-70%** get to a pharmacy;
- **48-66%** are picked up;
- **25-30%** are taken properly;
- **15-20%** are refilled as prescribed.

*Derived from IMS data

Get started on MTM services in your pharmacy

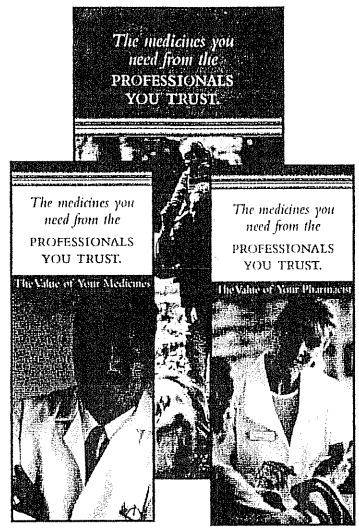
Some health plans are already reimbursing community pharmacies for providing MTM services. Here are a few things you can do to get started on providing MTM in your pharmacy:

- Check with management or contracted health plans to find out if there are opportunities for your pharmacy to provide MTM to eligible patients.
- Become an MTM expert: Visit *www.nacdsfoundation.org/mtm* for a wealth of resources, including a comprehensive training program developed by the National Association of Chain Drug Stores (NACDS) Foundation and the American Pharmacists Association (APhA).
- Identify patients at risk for medication-related problems and see if they are eligible for MTM through their insurance.

The Pharmacy Value Alliance: helping pharmacists demonstrate the value of prescription medication and the community pharmacist

Since 2003, the Pharmacy Value Alliance (PVA), a coalition of community pharmacy and pharmaceutical manufacturers, has been devoted to spreading the "dual value" message of medication and the important role of the community pharmacist. The group has developed a variety of resources to help pharmacists talk about value with their patients. All are available at *www.pharmacyvaluealliance.org*:

- **Helping Patients Achieve Better Outcomes Using Motivational Interviewing: Parts I and II** – Two online CE programs for pharmacists.
- **The Medicines You Need From the Professionals You Trust Consumer Brochure** – Explains the value of prescription medications and community pharmacists.
- **Value of Your Medicine bag stuffer** – Explains the value of prescription medicines and provides cost-saving options.
- **Value of Your Pharmacist bag stuffer** – Explains the valuable services pharmacists provide to their patients.
- **Pharmacist Opportunity Statements** – A list of opportunities for pharmacists to engage patients in conversations about value.
- **Pharmacy Technician Opportunity Statements** – A list of opportunities for pharmacy technicians to engage patients in conversations about value.



Pharmacy Value: Four take home points to remember and use

- You can prove pharmacists' value by simply telling patients what you do to keep them healthy.
- Introduce yourself to all of your patients! Studies show that patients that know their pharmacist's name are almost two times more likely to rate their service as higher quality than those who do not know their name.
- Become involved with MTM services! MTM provides an exciting opportunity for you to showcase your expertise while helping patients.
- You are the medication expert! Adherence remains a huge issue in health care and as the most accessible health care provider, you are in the best position to help.

The value of telling patients your name

During an extensive pilot program in four U.S. cities, the Pharmacy Value Alliance discovered that consumers who know their pharmacist's name were more likely to rate that pharmacist higher in terms of quality of service compared to consumers who did not know their pharmacist's name.

79% of consumers who knew their pharmacist's name gave the highest grade of "A" in terms of quality of service -- compared to 44% when they did not know their pharmacist's name.

Make sure to introduce yourself to your patients and communicate your value. Visit www.pharmacyvaluealliance.org for more information on pharmacy value.

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Visit our website at www.nacdsfoundation.org

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Through educational and research initiatives, the NACDS Foundation supports programs that advance the chain pharmacy industry for the benefit of the public it serves. In addition to its own initiatives, the NACDS Foundation supports other educational and charitable causes across the country.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Goal 4: Provide relevant information to consumers and licensees.

Outcome: Improved consumer awareness and licensee knowledge.

Objective 4.1 Measure:	Develop a minimum of 10 communication venues to the public by June 30, 2011. Number of communication venues developed to the public.
Tasks:	1. Assess the effectiveness of the board's educational materials and outreach: survey consumers to identify whether board-produced materials are valued and what new materials are desired. *Sept. 2006:* *Committee begins review of consumer outreach.* *Dec. 2006:* *Staff conducts assessment of the board's consumer outreach written materials. Material is identified for revision and update, future development, or evaluation for continued need.* *Jan. 2007:* *Drafts of board informational brochure and complaint process brochures are updated; brochures will undergo review.* *April 2007:* *Drafts of board informational brochure and complaint process brochures are provided to the Department of Consumer Affairs for review.* 2. Restructure the board's Web site to make it more user friendly. *July 2006:* *Web site modified to contain lists of disciplinary actions finalized each quarter and permit online access to public documents regarding board disciplinary actions taken against a licensee.* *March 2007:* *Web site modified by adding 14 links to obtain various information regarding Medication Safety and Drug Interactions.* *Web site modified by adding 7 links to obtain information from FDA regarding Medications and Medical Devices.* *March 2007:* *Work initiated on the latest State Web site design to be in place by November 2007.* 3. Work with the California Health Communication Partnership on integrated public information campaigns on health-care topics. *Sept. 2006:* *Committee continues collaboration with the partnership whose fall campaign is screening for prostate and breast cancer. Plans underway to work to promote generic drugs in the future.* *April 2007:* *Summary provided of the Fall 2006 campaign to raise awareness about breast cancer screening and prostate cancer sreening. No recent meetings of the partnership have occured.* 4. Continue collaboration with UCSF's Center for Consumer Self Care for pharmacist interns to develop consumer fact sheets on health topics. *Sept. 2006:* *Nine previously developed fact sheets are sent to a translation service to develop Spanish, Chinese, and Vietnamese versions of these materials. Four new fact sheets developed and undergoing review by the board.* *April 2007:* *Four draft fact sheets are still under review and the committee receives three new fact sheets. The committee determines that the board will expand the project beyond the Center for Consumer Self Care to include students from other Schools of Pharmacy.*

	5. Develop a Notice to Consumers to comply with requirements of AB 2583 (Nation, Chapter 487, Statutes of 2006) on patients' rights to secure legitimately prescribed medication from pharmacies. *Sept. 2006:* *Governor signs AB 2583.* *Oct. 2006:* *Committee advances draft regulation text for comment at the October Board Meeting. Board votes to create a second Notice to Consumers poster vs. adding additional language to current poster.* *Jan. 2007:* *Committee refines language to be advanced to the board. Board reviews, modifies, and sets for regulation notice the proposed language for a second Notice to Consumers poster.* *April 2007:* *Board reviews comments submitted in rulemaking process to adopt this regulation change.*

Objective 4.2	Develop 10 communication venues to licensees by June 30, 2011.
Measure:	Number of communication venues developed to licensees.
Tasks:	1. Publish The Script two times annually. *Sept. 2006:* *The Script published and mailed to pharmacies and wholesalers.* *Jan. 2007:* *The Script published and mailed to pharmacies and wholesalers.* 2. Develop board-sponsored continuing education programs in pharmacy law and coordinate presentation at local and annual professional association meetings throughout California. *1st Qtr 06/07:* *Board supervising inspectors present five CE programs on pharmacy law and the Board of Pharmacy to pharmacist associations statewide.* *Sept. 2006:* *Supervising Inspector Ming provides information on pharmacy law to 80 pharmacists and pharmacy technicians at a San Mateo Pharmacist Association.* *Supervising Inspector Ratcliff provides information on pharmacy law to the Sacramento Valley Society of Health System Pharmacists.* *Oct. 2006:* *Interim Executive Officer Herold presents Legislation and Regulation update at CSHP's Annual Seminar. Board also staffs information booth for licensees.* *Nov. 2006:* *Board Member Goldenberg speaks at the California Association of Health Facilities Convention in Palm Springs.* *Supervising Inspector Ming provides information on pharmacy law to UCSD students.* *Jan. 2007:* *Supervising Inspector Ming provides information on pharmacy law to the Indian Pharmacist Association.* *Feb. 2007:* *Executive Officer Herold provides information about the board at the CPhA's annual meeting.* *Feb. 2007:* *Board Member Hiura provides information about pharmacy law to pharmacists at a Korean pharmacist association meeting.* *March 2007:* *Supervising Inspector Nurse presents California's Electronic Pedigree requirements to the Generic Pharmaceutical Manufacturers Association annual meeting in Phoenix.* *March 2007:* *Supervising Inspector Ratcliff provides information about pharmacy law and the board to 80 UCSF students.* *March 2007:* *Former Board Member John Jones provides a law update to Western University students.* 3. Maintain important and timely licensee information on Web site. *1st Qtr 06/07:* *Added 50-year pharmacist recognition pages as a special feature.* *Updated license totals.* *Added enforcement actions for effective dates between April 1 and June 30, 2005.* *Changed definitions on license lookup to clarify license status.* *Posted board and committee meeting agendas and materials.* *Sent out subscriber alert notifications to the board's e-mail notification list, including two drug recalls.*

2nd Qtr 06/07:	*Unveiled new Web site of the board, and created new Web links.* *Revised and added new fax and contact information to speed communication with appropriate enforcement and licensing staff.* *Updated listing of 50 year pharmacists.* *Added frequently asked questions on emerging contraception.* *Updated listing of enforcement actions taken.* *Reviewed and updated board member biographies.* *Made corrections to the board's online lawbook.* *Added all agendas, meeting packets and minutes for board and committee meetings.* *Sent out nine subscriber alerts for important information added to the board's Web site.*
3rd Qtr 06/07:	*Completed updates to website to comply with SB 796.* *Updated copyright year.* *Updated links referring to California's and the governor's web pages.* *Added information about the denial of a registration or license.* *Added information about the new CPJE vendor.* *Added inspector and supervising inspector exam information.* *Revised information on our Contact Us page.* *Updated applications on the website to include mandatory reporting information.* *Updated public disclosure through Web Lookup to include discipline taken after January 2002.* *Updated listing of 50-year pharmacists.* *Added enforcement actions for effective dates between January 1 and March 30, 2007.* *Posted board and committee meeting agendas and materials.* *Sent out 19 subscriber alert notifications to the board's e-mail notification list.*

Objective 4.3	Participate in 12 forums, conferences and public education events annually.
Measure:	Number of forums participated.
Tasks:	1. Participate in forums, conferences and educational fairs. *Sept. 2006:* *Supervising Inspector Nurse provides presentation on California's e-pedigree requirements at Logi-Pharma's Annual Convention in Austin TX.* *Oct. 2006:* *Board hosts the three-day NABP Districts 7 & 8 Meeting. Topics include the FDA's pedigree requirements, the DEA's pseudoephedrine requirements, divergent intern requirements from state to state, and development of ethics programs for health professionals.* *Supervising Inspector Nurse provides presentations to national EPCglobal Convention (a standards setting organization) in Los Angeles on California's e-pedigree requirements for prescription drugs.* *Board staffs information booth at San Mateo Senior Fest where 600 people attend.* *Dec. 2006:* *Inspector Barnard and Public and Licensee Education Analyst Abbe staff information booth at the Sacramento AARP-sponsored Ask A Pharmacist event.* *Jan. 2007:* *Supervising Inspector Nurse provides presentation on California's e-pedigree requirements at Secure Pharma 2007, the supply chain security conference in Philadelphia.* *Feb. 2007:* *The board hosts an information booth for two days at CPhA's annual meeting.* *March 2007:* *Inspector Wong and Analyst Abbe staff information booth at the 2007 Consumer Protection Day forum in San Diego.*